PHYSICOCHEMICAL CHARACTERISATION AND BINDING PROPERTY OF POLYSACCHARIDE OF *SOLANUM BETACEUM CAV* IN TABLET FORMULATION

A Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY

CHENNAI – 600 032

In partial fulfillment of the requirements for the award of the Degree of

MASTER OF PHARMACY
IN
BRANCH-1 -PHARMACEUTICS

Submitted by

Mr. PRASANTH R.K

REGISTRATION NO: 261511403

Under the guidance of

Dr. S. MOHAN, M.Pharm, Ph.D.,

Principal and Head

Department of Pharmaceutics

KARPAGAM COLLEGE OF PHARMACY

S.F.762, OTHAKKALMANDAPAM

COIMBATORE- 641 032

April 2017

CERTIFICATE

CERTIFICATE

This is to certify that the dissertation work entitled **"PHYSICOCHEMICAL CHARACTERISATION AND BINDING PROPERTY OF POLYSACCHARIDE OF *SOLANUM BETACEUM CAV* FRUIT IN TABLET FORMULATION"** submitted by **Mr.Prasanth R.K (Reg No:261511403)**. The work mentioned in the dissertation was carried out at the **Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** under the guidance of **Dr.S.MOHAN, M.Pharm., Ph.D., Principal & Head, Department of Pharmaceutics** for partial fulfillment for the Degree of **Master of Pharmacy** and is forwarded to **The Tamilnadu Dr.M.G.R. Medical University, Chennai** during the academic year 2016-2017.

Dr.S.MOHAN, M.Pharm, Ph.D.,

Principal

CERTIFICATE

This is to certify that the dissertation work entitled **"PHYSICOCHEMICAL CHARACTERISATION AND BINDING PROPERTY OF POLYSACCHARIDE OF *SOLANUM BETACEUM CAV* FRUIT IN TABLET FORMULATION"** submitted by **Mr.Prasanth R.K (Reg No:261511403)** to **The Tamilnadu Dr.M.G.R. Medical University, Chennai** in partial fulfillment for the Degree of **Master of Pharmacy in Pharmaceutics** is a bonafied work carried out by the candidate under my guidance at the **Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** during the academic year 2016-2017.

Dr.S.MOHAN, M.Pharm, Ph.D.,

Professor & Head,

Department of Pharmaceutics,

(Guide)

CERTIFICATE

This is to certify that the dissertation work entitled **"PHYSICOCHEMICAL CHARACTERISATION AND EVALUATION OF BINDING PROPERTY OF *SOLANUM BETACEUM CAV* IN FORMULATION OF TABLETS"** submitted by **Mr.Prasanth R.K (Reg No:261511403)** to **The Tamilnadu Dr.M.G.R. Medical University, Chennai** in partial fulfillment for the Degree of **Master of Pharmacy in Pharmaceutics** is a bonafied work carried out by the candidate under my co-guidance at the **Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** during the academic year 2016-2017.

Mrs.Gayathri, M.Pharm.,

Associate Professor,

Department of Pharmaceutics,

(Co-Guide)

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled **"PHYSICOCHEMICAL CHARACTERISATION AND BINDING PROPERTY OF POLYSACCHARIDE OF *SOLANUM BETACEUM CAV* FRUIT IN TABLET FORMULATION"** submitted by **Mr.Prasanth R.K (Reg No:261511403)** to **The Tamilnadu Dr.M.G.R. Medical University, Chennai** in partial fulfillment for the Degree of **Master of Pharmacy in Pharmaceutics** is a bonafied work carried out during the academic year 2016-2017 by the candidate at the **Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** and was evaluated by us.

Examination Centre:-

Date:-

Internal Examiner

External Examiner

DECLARATION

I hereby declare that this dissertation work entitled **"PHYSICOCHEMICAL CHARACTERISATION AND BINDING PROPERTY OF POLYSACCHARIDE OF *SOLANUM BETACEUM CAV* FRUIT IN TABLET FORMULATION"** submitted by **Mr.Prasanth R.K (Reg No:261511403)** submitted by me, in partial fulfillment for the Degree of **Master of Pharmacy in Pharmaceutics** to **The Tamilnadu Dr.M.G.R Medical University, Chennai** is the result of my original and independent research work carried out under the guidance of **Dr.S.MOHAN, M.Pharm, Ph.D., Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** during the academic year 2016-2017.

I hereby further declare that the **Department of Pharmaceutics**, **Karpagam College of Pharmacy**, **Coimbatore** shall have the rights to preserve, use and disseminate this dissertation in print or electronic format for academic or research purpose.

Signature of the Candidate

Reg.no.(261511403)

ACKNOWLEDGEMENT

ACKNOWLEDGEMENT

Apart from my effort, the success of this dissertation mainly depends on the encouragement and guidance of many others. I take this opportunity to express my gratitude to the people who have been instrumental behind the successful completion of this task.

First and foremost, I wish to express my thanks to holiness for his love and unseen guidance throughout my work.

Any successful completion of task would become incomplete without mentioning people who made it possible with their guidance and encouragement.

I would like to express my profound thanks to my beloved Parents father **Mr.M.R. Krishnan** and mother **Mrs.K.Amutha** brought me this world and encouragements in all my life carriers and my sister **Ms.K.Priya** for their support and encouragements in all these two years.

Firstly, I extended thanks to **Dr.VasanthaKumar, Chairman, Karpagam Institution, Coimbatore** for the facilities provided by him to carry out the study in an efficient manner..

I express my genuine heartfelt gratitude and sincere thanks to my esteemed guide **Dr.S.Mohan, M.Pharm,Ph.D., Principal and Head Department of Pharmaceutics, Karpagam College of Pharmacy** for his valuable suggestions, encouragement, motivation, inspiring, guidance and co-operation throughout my dissertation work. I thank him for his encouragement and effort, without him this work would not have been completed or written.

I express my sincere thanks to my esteemed co-guide **Mrs.Gayathri, M.Pharm, Associate Professor, Department of Pharmaceutics, Karpagam College of Pharmacy** for his valuable suggestions, encouragement, motivation, inspiring, guidance and co-operation throughout my dissertation work.

I would like to express heartfelt thanks to **Kreszent Pharma, Pondicherry** and **Karpagam pharma LLP**, **Coimbatore** for providing drug and excipients and their support and encouragements.

I want to express my gratitude to my beloved staff **Mr. Benedict Jose, M.Pharm, Associate Professor, Department of Pharmaceutics, Karpagam College of Pharmacy** for support and encouragements.

I want to express my gratitude to **Mr. Antony Doss** Laboratory Technician for their sincere concern and help.

I express my gratitude to **Library staff** and **other Lab Technicians of Karpagam College of Pharmacy** and all those helped me in the completion of my entire work.

I want to express my thanks to **all Faculty of Karpagam College of Pharmacy**, where directly or indirectly gave a helping hand to me while carrying out the dissertation.

I would like to express heartfelt thanks to my ever loving senior **Mr.Gowthaman, M.Pharm, DIPC., Production Executive**, **Karpagam Pharma LLP, Coimbatore**.

I would like to express heartfelt thanks to my friends **S.Pradeesh mohan, Sadagoban.V.R,** and **Final Year B.Pharmacy Students (*2016-2017*) batch**.

Finally I would like to express heartfelt thanks to **Nature of God** to give invisible guidance throughout my life carriers, studies and dissertation work.

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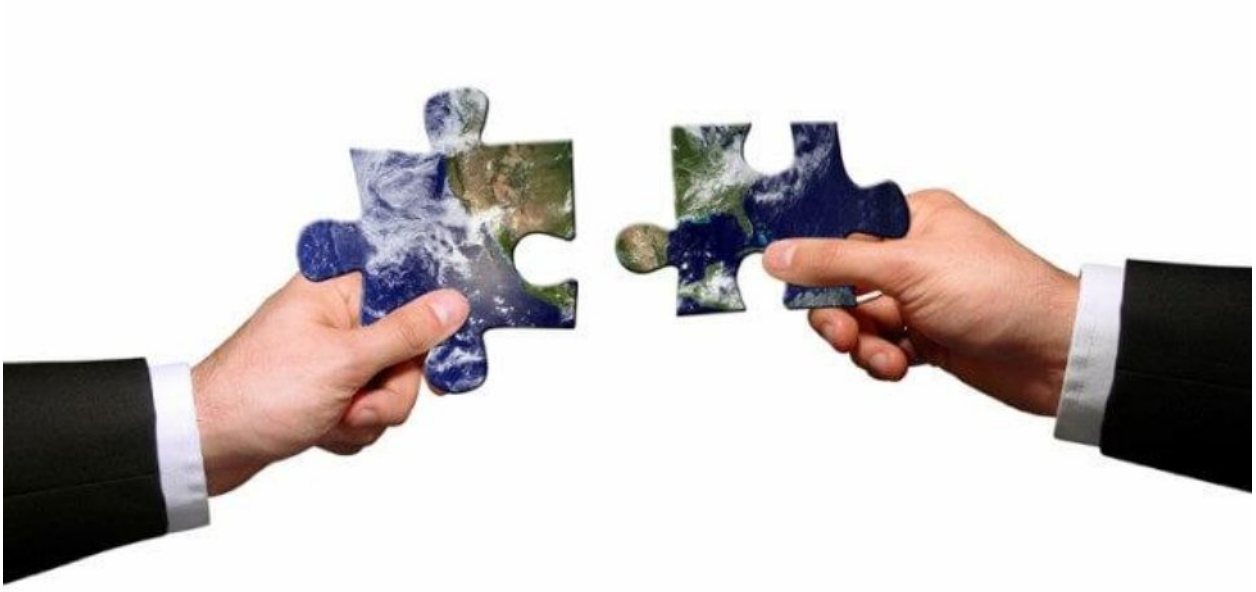
LIST OF ABBREVATIONS

CPS	Centipoise
DSC	Differential scanning colorimetry
FTIR	Fourier transform infra-red
F1 to F9	Formulation codes of formulation using binding agent
SB	*Solanum Betaceum cav*
Kg	Kilogram
Mg	Milligram
Mins	Minutes
MPS	Sodium Methylparaben
PPS	Sodium Propylparaben
PVP	Polyvinylpyrrolidone
UV	Ultraviolet
W/V	Weight by Volume
XRD	x-ray diffraction
µg/ml	Microgram Per milliliter
%	Percentage



INTRODUCTION

INTRODUCTION

Binders are pharmaceutical excipients that are commonly employed in tablet formulation to exert cohesion on the powder mix which there by improves the flow properties on the granules. Binders cause aggregation of powders which forms granules through the process of granulation. Binders promote the formation of strong cohesive bonds between particles and thus modifies the cohesive properties of the granules.

The cohesiveness imparted to the tablet formulation ensure that the tablet remains intact after compression. Binders improve the flow properties by formulation of granules of desired hardness and size. The quantity of binder used has considerable influence on the characteristics of the compressed tablets.

An ideal binder should have good binding properties, as determined by compressibility under pressure, high plasticity, low elasticity and small particle size. Small particle size facilitates even distribution of the binder through the inter-particulate void spaces in a tablet. Uniform binder distribution in the tablet results in decreased pore structure and subsequent enhancement in table crushing strength. To reduce friability, a binder with high plastic properties (high deformability) is essential. A further requirement for a good binder is low hygroscopicity. Excessive uptake of moisture (greater than 5%) or high moisture content can lead to instability and sticking during production.

Binder can be added either as a solution or as a dry powder. The same amount of binder in solution will be more effective than if it were dispersed in a dry form and moistened with a solvent. Binder are added as a dry powder with other excipients in dry granulation (roller compaction, slugging) or as an extra granular excipients in a wet granulation tablet formulation. Binder are also added as a dry powder with other intra granular excipients in wet granulation. When the granulating fluid is added, the binder may dissolve partially or completely and then exhibit adhesive binding properties in helping granules to form. Water is the most common granulating fluid, very occasionally in a co solvent e.g. Ethanol. Common traditional solution binders are acacia, sodium alginate, starch, sugar and gelatin. Important dry binders are pre gelatinized starch, celluloses (methyl cellulose, hydroxyl propyl methyl cellulose) and cross

linked poly vinyl pyrrolidine (PVP). Both the solution and dry binders are included in the formulation at relatively low concentrations typically 2-10 % w /w.

Binder are also added as a dry powder with other intra granular excipients in wet granulation. When the granulating fluid is added, the binder may dissolve partially or completely and then exhibit adhesive binding properties in helping granules to form in the formulation of tablets may be of natural, semi synthetic or synthetic type. Synthetic polymers are mostly used due to their ease of availability, processing and less time consuming for manufacture of those polymers. Some of the synthetic polymers that are commonly used in the formulation of tablets are as follows: i) Poly vinyl pyrrolidine: It is a synthetic polymer available in range of molecular weights or viscosities. It can be used either dry or in solution form. Soluble in water and ethanol. Normal usage concentration is 2- 8 %.ii) Hydroxy propyl methyl cellulose: Available in a range of molecular weights and viscosities. Soluble in water and ethanol. It can be used as anhydrous binder in moisture sensitive compounds. Normal usage concentration is 2- 8 %.iii) Methyl cellulose: Low viscosity grades are most widely used. Usage concentration is 1- 5 %.

However the synthetic polymers posses the following disadvantages:

High cost, toxicity, environmental pollution during synthesis, non- renewable sources, side effects, poor patient compliance.

Acute and chronic adverse effects, skin and eye irritation have been observed in workers handling methyl methacrylate and poly- (methyl methacrylate)

Carbomer dust is irritating to the eyes, mucous membrances and respiratory tract

Bio degradable polymers used in tissue engineering application possess poor bio compatibility, release of acidic degradation products, poor processing ability and rapid loss of mechanical properties during degradation.[1,2,5]

NATURAL POLYMERS:

Nature has gifted India with great variety of flora and fanna. For centuries man has made effective use of materials of natural origin in the medical and pharmaceutical field. Today, the whole world is increasingly interested in natural drugs and excipients.

In recent years, plant derived polymers have evolved tremendous interest due to their diverse pharmaceutical application such as diluents, binder, disintegrant in tablets, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels and bases in suppository. They are also used in cosmetics, textiles, paints and paper making.

These polymers such as natural gums and mucilage are biocompatible, cheap and easily available and are preferable than semi synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action and non-irritant nature.

Furthermore, they can be modified to obtain tailor made materials for drug delivery systems allowing them to compete with the synthetic products that are commercially available. Many kinds of natural gums are used in food industry and are regarded as safe for human consumption.

Drug products designed to reduce the frequency of dosing by modifying the rate of drug absorption have been available for many years.

Regular research is going on for the use of naturally occurring biocompatible polymeric material in designing of dosage form for oral controlled release administration. Natural gums are biodegradable and nontoxic, which hydrate and swell on contact with aqueous media, so these have been used for the preparation of dosage form. Protein, enzymes, muscle fibres, polysaccharides and gummy exudates are the natural polymers being used effectively in formulating variety of pharmaceutical products.

The plant based polymer have been studied for their application in different pharmaceutical dosage forms like matrix controlled system, film coating agents, buccal films, microspheres, nano particles, viscous formulations like ophthalmic solution, suspension, implants and their applicability and efficacy have been proven. Then have been utilized as viscosity enhancers,

stabilizers, disintegrants, solubilizers, emulsifiers, suspending agents, gelling agents, bioadhesives and binders in the above mentioned formulations.[8]

Advantage of natural polymers in pharmaceutical science:

The following are a number of advantages of natural plant- based materials

a) Biodegradable:

Naturally available biodegradable polymers are produced by all living organisms. They represent truly renewable source and they have no adverse impact on humans or environmental health (eg. Skin and eye irritation).

b) Biocompatible and nontoxic:

Chemically, nearly all of these plant materials are carbohydrates composed of repeating sugar (monosaccharide) units. Hence, they are non- toxic.

c) Low cost:

It is always cheaper to use natural sources. The production cost is also much lower compared with that for synthetic material.

d) Environmental- friendly processing:

Gums and mucilage from different sources are easily collected in different seasons in large quantities due to the simple production processes involved.

e) Local availability:

In developing countries, government promotes the production of plant like guar gum and tragacanth because of the wide application in a variety of industries.

f) Better patient tolerance as well public acceptance:

There is less chance of side and adverse effects with naturals materials compared with Synthetic one.

g) Edible sources:

Most gums and mucilage are obtained from edible sources.

Eg. Potato starch, corn starch, cassava starch.

Disadvantages of natural polymers:

a) Microbial contamination:

The equilibrium moisture content present in gums and mucilage is normally 10% or More, and, structurally, they are carbohydrates and, so there is a chance of microbial contamination. However this can be prevented by proper handling and use of preservatives.

b) Batch to batch variation:

Synthetic manufacturing is a controlled procedure with fixed quantities of Ingredients, while production of gums and mucilage is dependent on environmental and seasonal Factors.

c) Uncontrolled rate of hydration:

Due to difference in the collection of natural materials at different time, as well as differences in region, species and climate conditions the percentage of chemical constituents present in a given material may vary. There is need to develop suitable monograph on available gums and mucilage.

d) Reduced viscosity on storage:

Normally, when gums and mucilage come into contact with water there is an increase in the viscosity of the formulation. Due to the complex nature of gums and mucilage (monosaccharide to polysaccharides and their derivatives), it has been found that after storage

There is reduction in viscosity. Drug products designed to reduce the frequency of dosing by modifying the rate of drug absorption have been available for many years. Regular research is going on for the use of naturally occurring biocompatible polymeric material in designing of dosage form for oral controlled release administration. Natural gums are biodegradable and nontoxic, which hydrate and swell on contact with aqueous media, so these have been used for the preparation of dosage form.[9,]

Gum mucilage isolated from the bark of *Grewia optiva* used as a binder for tablets. An increase in binder concentration resulted in a corresponding increase in tensile strength. *Grewia optiva* gum mucilage could be considered as a cheap, economic and easily available tablet binder. The mucilage of *Hibiscus sabdariffa* fruit calyces was evaluated for its binding property in the formulation of tablet dosage forms. The bark of the plant, *Remussatia vivpara* belonging to the family Araceae, contains a huge amount of mucilage. The mucilage exhibited good binding property, which upon increase in concentration showed small retardation in drug release from tablet.[11]

Plant polysaccharides have been shown to be useful for the construction of drug delivery system for specific drug delivery. Gum acacia is often used as plasticizer and tablet binder. The gum acacia has been recognized as an acidic polysaccharide containing D- galactose, L- arabinose, L-rhamnose and D- galacturonic acid. Tamarind gum contains xyloglycon. Both of these are hydrophilic polymer and had been limited for use as gelling, thickening, suspending and emulsifying agents. Dendrophthhoe falcate, family- Loranthaceae, is a dried as well fresh stem parasitic on *Magnifera indica*. The mucilage was evaluated as a good binding agent for uncoated tablets. Citrus fruit peels, a byproduct of citrus fruits processing, were investigated as a source of pectin. Citrus peel pectin can act as excellent binder in dosage forms. Since it is of natural origin and citrus peel available at low cost it may prove to be better binder over commercially used synthetic binder.[13]

The starch extracted from *Zingiber officinale*, was evaluated for evaluated for the binding and disintegrant property in the formulation of tablets. The gum of *Moringa oleifera* was used as a binder and release retardant in tablet formulation. Okra gum was extracted from Okra fruit

(Hibiscus esculentus) when used as a tablet binder, it prolongs the dissolution rate of some slightly soluble drugs and hence may be good candidate for sustained release formulations.[23,27]

Dried date palm fruit is a natural product which is non- toxic, biodegradable and biocompatible that can be employed as a pharmaceutical binding agent for immediate release dosage forms. Starch extracted from two varities of millet- *Pennisetum glaucum* and *pennisetum americanum,* are used as a binder to yield tablets of good friability, crushing strength and disintegration time. Fenugreek (Trigonelle foenum- graecum) seeds produce high viscosity mucilage at low concentration levels. When used as a binder, the mucilage sustains the dissolution rate of water soluble drugs.[1]

The mucilage obtained from the seeds of *Cordia roothii Roxb* and *Cordia dichotoma Forst* is studied for binding property. The endospermic mucilage of the seeds of *Delonix regia* (goldmohur) possess binding was evaluated for binding property.

The aromatic gum resin galbanum obtained from wounds made in the stem of *Ferula gummosa Boiss* belonging to the family Apiaceae was investigated as binder in tablets sesbania gum, derived from the endosperm of seeds of the plant *Sesbania grandiflora* belonging to the family Leguminosae is studied for microbially triggered colon specific drug delivery. *Oriza sativa* was investigated as a matrix forming polymer in the oral sustained release formulations. The seeds of *Artocarpus heterophyllus* fruit, gum mucilage of *Cissus populnea* and *Accassia Senegal* are evaluated for binding property. *Moringa olifera* gum, Gum *odina*, *Cassia tora* are also investigated for binding property. The starch obtained from barley crop (Hordeum vulgare) was evaluated for binding property.[20,24,26]

In the present work, the polymer used as a binding agent is extracted from the fruits of ***solanum betaceum cav*** belongs to the family ***solaneacea.*** The tree is native to India and Southern China, but now found throughout the tropics.

Commom name: tree tomato , tamarillo, mara thakkali in tamil.

USES:

As the tamarillo fruit contains a number of nutrients., it is used for several therapeutic purposes. Tamarillos contain high levels of pottassium, which is useful in controlling the blood pressure and heart rate. This essential mineral is useful for balancing the harmful actions of sodium on the heart. Aside from potassium, tamarillos also contain magnesium as well as various other minerals, which are necessary for the normal functioning of our cardiovascular system. Tamarillo also contains elevated levels of dietary fiber, which is useful in slowing down the absorption of bad or LDL cholesterols in our body. This fruit possesses antioxidant activity and, hence, it is useful in protecting the heart from any type of oxidative stress. At the same time, tamarillos also lessen the chances of developing cardiac disorders, including stroke and heart attack.

Tamarillos enclose citric acid, which is believed to be useful in preventing the development as well as growth of kidney stone. In fact, citric acid offers a number of protective benefits by means of flushing out surplus calcium and uric acid from our body along with excreta. The acidic taste of tamarillo fruits is attributed to citric acid enclosed by them. When you incorporate the tree tomato or tamarillo into your diet, it lessens the chances of kidney stone development and growth. Nevertheless, there is no scientific evidence that proves that consumption of tamarillos help in preventing kidney stones.

Tamarillos or tree tomatoes are rich in phytonutrient content and they aid in reducing the chances of developing certain forms of cancer, since they possess antioxidant properties. It has been established that anthrocynanins possess anti-cancer qualities. Similarly, studies undertaken in laboratories have shown that lycopene also works to slow down cancer cell growth. Tamarillos possess antioxidant properties and, hence, consuming these fruits helps to protect the cells in our body from oxidative stress, thereby preventing them from becoming cancerous.

Finds of most recent studies have indicated that free radicals as well as oxidative stress are responsible for various disease and health conditions. Free radicals are detrimental as they damage the cells in our body, thereby impairing their normal functioning. Tamarillos contain phytonutrients that offer outstanding antioxidant activity and, at the same time, reduce the

chances of developing degenerative diseases like diabetes and heart problems, cancer, cataracts, Alzheimer's diseases, Parkinsons disease and so on. The antioxidant property of tree tomato has been attributed to the presence of vitamins A, C and E along with a number of other phytonutrients.

It is unfortunate that people are yet to fully utilize the antioxidant properties of tamarillos. In fact, the flesh as well as the peel of this fruit is loaded with antioxidants. Findings of several scientific studies have revealed that the antioxidant activity of tamarillo peel is higher owing to the presence of flavanoids and phenols, while the antioxidant activity of the tree tomato flesh is attributed to the presence of carotenoids and anthocyanins

LITERATURE REVIEW

LITERATURE REVIEW

Musa.H , et.al., [1]carried out the evaluation of Millet(*Pennisetum glaucum* and *Pennisetum americanum*) starches as tablet binders. Starch extracted from the two variety of millets are used as binders in the formulation of Paracetamol tablets in comparison with Maize starch formulations. Increasing the concentration of the Millet starches as binder gave Paracetamol tablets of good friability, crushing strength and disintegration time.

Rishaba malviya , et.al., [5] carried out the formulation, evaluation and comparsion of sustained release matrix tablets of Diclofenac Sodium using Natural polymers as release modifier. Gum acacia and Tamariand gum are used as relase modifiers to formulate sustained release matrix tablets of Diclofenac sodium. The drug release from matrix tablets prepared by using natural polymers can be sustained for more than 12 hours and the drugs release vary with concentration of polymer in matrix tablets.

Olubunni olayemi , et.al., [8] evaluated *Brachystegia eurycoma* seed mucilage for use as a tablet binder in metronidazole formulations in comparison with gelatin. The tablets had a rapid dissolution rate which indicates the efficacy of *Brachystegia eurycoma* seed mucilage as a binder where fast release of drug is desired.

Kothawade S.N , et.al., [9]carried out the preliminary evaluation of *Dendrophthoe falcate* mucilage as Tablet Binder. The mucilage of *Dendrophthoe falcate* was evaluated as a binder for pharmaceutical dosage forms. The increased concentration of mucilage showed small retardation in drug release from tablet. It was found to be useful for the preparation of uncoated tablet dosage forms.

Nilesh R. Khule , et.al., [10] extracted pectin from citrus fruit peel and use as natural binder in paracetamol tablet. Citrus fruit peel, a byproduct of citrus fruit processing, were investigated as a source of pectin. Pectin assess its binding property in tablets using paracetamol as model drug. Since it is of natural origin and citrus peels available at low cost it may prove to be better binder over commercially used synthetic binders.

Vijay J Kumar , et.al., [11] carried out a work on potential natural tablet binder form *Grewia optiva*. Gum mucilage obtained from the bark of *Grewia optiva* is used as a tablet binder for paracetamol tablets. An increase in binder concentration resulted in a corresponding increase in tensile strength. The mucilage showed good flow properties and excellent swelling ratio. *Grewia optiva* gum mucilage could be considered as a cheap, economic and easily available tablet binder.

Pranati Srivatsava , et.al., [12] carried out the formulation and evaluation of Paracetamol tablets to assess binding property of orange peel pectin. The pectin extracted from orange fruit peels was assessed for binding property in tablets using paracetamol as model drug. Orange peel pectin can act as excellent binder in dosage forms.

Anoop kumar sing , et.al., [13] evaluated *Mangifera indica* gum as tablet binder. The gum of *Mangifera indica*(mango) was used as a tablet binder in the formulation of paracetamol tablets, in comparison with gum acacia as a standard binder. The friability valued decreased with increase in binder concentration. The tablet hardness and disintegration time increased with increase in binder concentration.

P. Padmakumari , et.al., [16] evaluated the fruit calyces mucilage of *Hibiscus sabdariffa Linn* as tablet binder. The mucilage of *Hibiscus sabdariffa* fruit calyces was evaluated for its binding property using Diclofenac Sodium as standard drug. Tablet hardness and disintegration time was increased with increasing binder concentration and friability values were decreased with increase in binder concentration. Therefore the mucilage could be used well as a binding agent in the formulation of tablet dosage forms.

Shelke.S.P , et.al., [17] carried out the preliminary evalution of *Remusatia vivipara* mucilage as tablet binder. The bark of the plant *Remusatia vivipara*, family- Aracea, contains a huge amount of mucilage. It was used as a binding agent for paracetamol tablets. The increased concentration of mucilage showed small retardation in drug release from tablet. The mucilage exhibit good binding properties for uncoated tablets.

Gangurde A.B , et.al., [18] carried out the preliminary evaluation of *Bauhinia racemosa Lamcaesalphinaceae* seed mucilage as tablet binder. The mucilage of the seed was used as a binder to formulate Amoxicillin trihydrate tablets. The drug release from tablets decreased with increase in concentration of the mucilage. It was found to be useful as tablet binder and granulating agent for wet granulation method.

Poornima M.Malagi , et.al., [19] evaluated sericin as a binder in the formulation of Diclofenac Sodium tablet adopting fully factorial design. Sericin, a gummy silk protein, has been evaluated as a binder in the formulation of Diclofenac Sodium tablets by wet granulaton techniques. The study has given a preliminary insight into the basic binding property. The polymeric chain in sericin offers numerous ways to produce excipients with desired properties for extended release or for tagging specific drugs molecules.

Bharath.S.,et.al.,[20]carried out the extraction of polysaccharide polymer from *Dioscoreatrifida* and evaluation as a tablet binder. The starch from yam was evaluated as binder for tablet in comparison with potato starch, corn starch, gelatin and acacia in the formulation of ibuprofen based tablets. The high starch content of yam tubers (70- 80%dry weight) has made them a potential source of starch that could be exploited commercially. The binder capacity of polymer could be depicted in the order of gelatin> acacia> potato> yam starch> corn starch.

Senthilselvi.R , et.al., [21] evaluated the mucilage of *prosopis juliflora* as tablet binder. The hydrophilic mucilage from the seeds of the plant *prosopis juliflora* belonging to the family Mimosaceae is used as a mucilage in the tablet formulation of Diclofenac Sodium. The tablet produced a sticky film of hydration on the surface, which reduce the drug release rate. This mucilage can also be used for sustaining the drug release from tablets.

Chalapathi.V , et.al., [22] formulated paracetamol tablet a novel binder isolated from *Manihot esculenta L.* the starch mucilage obtained from the roots of *Manihot esculenta L.*

commonly named as cassava, tapioca is used as binder to formulate paracetamol tablets. It was found to possess higher binding efficiency.

Basawaraj S. Patil , et.al., [23] evaluated the properties of *Zingiber officinale* starch as a novel tablet binder. The starch extracted from ginger rhizome was evaluated as a binder for tablets in comparison with potato starch in chloroquine phosphate based tablets.

Patil D.N , et.al., [24] carried out the preparation and evaluation of *Aegle marmelos* gum as tablet binder. *Aegle marmelos* gum as tablet binder. *Aegle marmeles* fruit gum is evaluated for the binding property in the formulation of paracetamol tablets. The increased concentration of gum showed a retardation in drug release from tablets.

Panda.D.S , et.al., [26] carried out the evaluation of gum of *Moringa oleifera* as a binder and release retardant in tablet formulation. Gum of *Moringa oleifera* was used as a binder and release retardant in the formulation of Propranolol hydrochloride tablets. Calcium sulphate dehydrate and lactose are used as diluents. The drug release increased with increasing proportion of excipient and decreased proportion of the gum irrespective of the solubility characteristics of the excipient. The excipient would either enhance dissolution or erosion mechanism, depending on the solubility of the excipient, which compensates for the slowing diffusion rate through the gradually increasing gel layer by creating greater porosity for the drug pathway.

Tavakoli.N , et.al., [27]studied the characterization and evaluation of okra gum as a tablet binder. Okra gum extracted from the pods of Okra fruit(*Hibiscus esculentus*). The binder effectiveness was evaluated with two models including a placebo formulation (lactose) and drug formulation (Acetaminophen, Ibuprufen and Calcium acetate). Corn starch and PVP were employed as standard binders for comparison. Okra gum prolongs the dissolution rate of some slightly soluble drugs and hence may be good candidate for sustained release formulations.

Ngwuluka.N.C , et.al.,[48] carried out the formulation and evaluation of Paracetamol tablet using the dried fruit of *Phoenix dactilifera Linn* as an excipient. Dried and milled date palm fruit was evaluated for its properties in comparison with acacia and tragacanth. The tablets manufactured using dried date palm was found to be less friable than manufactured using acacia and tragacanth. Therefore, dried date palm fruit may be expored as a pharmaceutical excipients.

Naser Tavakoli , et.al., [50] evaluated *Trigonellafoenum- graecum* seeds mucilage as a novel binder. The mucilage of fenugreek seed was extracted as a tablet binder in three different model drugs in terms of solubility- Calcium acetate, Theophylline and Ibuprufen. Corn starch and PVK K30 were selected as standard binder. The binder of fenugreek seed mucilage sustains the dissolution tare of water soluble drugs.

Nisarg C.Patel , et.al., [53]studied the binding property of *Cytonia vulgaris* seed mucilage in the formulation of parcetamol tablets. It was compared with that of acacia. The results conclude that *Cytonia vulgaris* possess the binding property equivalent to that of acacia.

Archana , et.al., [54] studied *Lepidium sativum* seed mucilage as a disintegrant in the formulation of orally disintegrating tablets of Metformin by direct compression. Results concluded that *Lepidium sativum* could be used as a disintegrant at low concentration of 2.5% w/v in tablet formulation.

Shivani Singh , et.al., [55] studied the mucilage obtained from *Cinnamomum tamala Nees* (Bay leaves) belonging to the family Lauraceae as a binding agent in the formulation of Paracetamol tablets. The results conclude that higher concentration of mucilage is required to obtain desired binding property.

Kwabena Ofori-Kwaye , et.al., [56]carried out the binding effect of purified Cashew tree gum obtained from *Anocardium accidentale* Linn belonging to the family-Anacardiaceae in the preparation of Metronidazole tablets. The tablets showed more than 94% release in 45minutes. Therefore it could be used as a binding in the conventional tablets.

Singh.S , et.al., [57] investigated the mucilage of *Cassia sophers Linn*, a common herbaceous plant belonging to the family *Caeselphiniaces* as a binding agent in the formulation o DiltiazemHcl tablets. The results conclude that the binding property of *Cassia sophera* mucilage is almost equivalent to Acacia.

Vidyasagar.g , et.al.,[58] evaluated the cordial fruit mucilages of *Cordia roothii Roxb, Cordia dichotoma Forst* as a binding agent in the prepareation of Paracetamol tablet.

Kale.H , et.al.,[59]studied the binding property of Goldmohur obtained from *Delonix regia* seeds in the formulation of Calcium carbonate tablets and compared with that of starch. The results conclude that the endospermic mucilage of *Delonix regia* seeds possess comparable binding as that of starch.

Reza Enauyutiford , et.al.,[60] carried out the assessment of Galbanum gum obtained from *Ferula gummosa Boiss* (family- Apiaceae) in the formulation os Acetaminophen and Calcium carbonate tablets. The binding property was compared with that of PVP and Acacia. The order of binding property was found to be PVP > Acacia > Galbanum gum.

Bireshkumar sarkar,et.al.,[61]studied of sesbania gum obtained from *Sesbania grandiflora*(family- Leguminosae)in microbially triggered drug delivery. The results conclude that Sesbania gum is a potential colon specific drug delivery carrier.

Rahul Thube , et.al., [62]evaluated Oriza as a matrix forming polymer in the formulation of Diclofenac sodium sustained release tablets. The results conclude that *Oriza sativa* prolongs the release of Diclofenac sodium from matrix tablets. Thus *Oriza sativa* could be used in the oral sustained release formulation.

Narkhed Sachin.B , et.al.,[63] carried out the binding of isolated mucilages of the seeds of *Artocarous heterophyllus*. It was compared with that of starch. From the results, it could be concluded that *Artocarpus heterophyllus* fruit possesses comparable binding properties.

Vishnumurthy Vummaneni , et.al., [86] studied the sffect of natural hydrophilic polymers like Guar gum, Pectin, Gum tragacanth and Xanthan gum in the formulation of Frusemide sustained release matrix tablets. Matrix tablets formulated with Guar gum showed a better controlled release than those with other polymers.

B raja,B. Panda , et.al., [87]evaluated of binders efficiency of different natural gums in tableting process. The physical properties of the granules, the tableting performance and the physical characteristics of the tablet were evaluated.

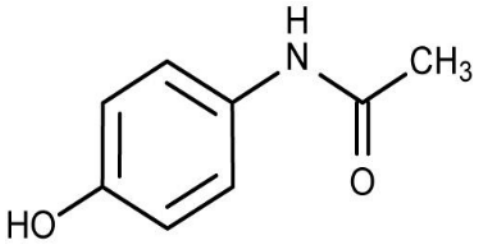
Amir Shaik , et.al., [88]studied the effects of Xanthan, Guar and K- Carrabeanan gum on the release of Ambroxol Hel from sustained release matrices. The results conclude that the drug retardation was highest from xanthan gum matrices and low from guar gum matrices.

DRUG PROFILE

DRUG PROFILE

PARACETAMOL:

Structure:



Molecular formula: $C_8H_9NO_2$

Molecular mass: 151.163g/mol

IUPAC name: N-(4-hydroxyphenyl) ethanamide

N-(4-hydroxyphenyl) acetamide

Category:

It is widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer) Paracetamol is classified as a mild analgesic. It is commonly used for the relief of headaches and other minor aches and pains and is a major ingredient in numerous cold and flu remedies. In combination with opioid analgesics, paracetamol can also be used in the management of more severe pain such as post-surgical pain and providing palliative care in advanced cancer patients. Though paracetamol is used to treat inflammatory pain, it is not generally classified as an NSAID because it exhibits only weak anti-inflammatory activity.

Physical state: solid

Dosage form:

Paracetamol is available in a tablet, capsules, liquid, suspension, and suppository, intravenous, intramuscular and Effervescent form.

Melting point: 169 °C (336°F)

Solubility:

Freely soluble in ethanol (95%) and in acetone; sparingly soluble in water, very slightly soluble in dichloromethane and in ether.

Mechanism of action:

The mechanism of action of paracetamol is not completely understood. The main mechanism proposed is the inhibition of cyclooxygenase (COX), and recent findings suggest that it is highly selective for COX-2.

Absorption:

After oral administration it is rapidly absorbed by the GI tract.

Distribution:

Volume of distribution is roughly 50 L.

Metabolism:

Paracetamol is metabolized primarily in the liver, into toxic and non-toxic products. Three metabolic pathways are notable:

- Glucuronidation (45-55%)
- Sulfation (sulfate conjugation) accounts for 20-30%.
- N-hydroxylation and dehydration, then GSH conjugation, accounts for less than 15%. The hepatic cytochrome P450 enzyme system metabolizes paracetamol, forming a minor yet significant alkylating metabolite known as NAPQI (n-acetyl-p-benzoquinone imine)(also known as N-acetylimidoquinone). NAPQI is then irreversibly conjugated with the sulfhydryl groups of glutathione.

Excretion: Urine (85-90%)

Bioavailability: 63-89%

Protein binding: 10-25%

Plasma half-life: 1-4 hours

Drug interaction:

Enhances oral anticoagulant activity. Absorption increased by metoclopramide. Absorption reduced by pethidine, propanthline. Alcohol (chronic use) potentiates hepatotoxicity by paracetamol.

Side effect:

Acute overdoses of paracetamol can cause potentially fatal liver damage.

Dose:

- Oral: Mild to moderate pain and fever.
- Adult: 500mg to 1000mg every 4-6 hrs up to max of 4 gram daily.
- Child: under 6 months- 10mg/kg body weight.
- 3 months to 1 year: 60-120mg.
- 1-5 year: 120-250mg.
- 6-12year: 250-500mg.

The above dose 3-4 times daily as required.

Routes:

Oral, intramuscular, intravenous, rectal.

Storage:

Store in well closed container and protect from light.[28]

EXCIPIENTS PROFILE

EXCIPIENTS PROFILE

STARCH:-

Maize starch powder is a Polysaccharide obtained from the caryopsis of maize or corn.

Synonyms: Maize starch

Appearance: Fine white or slightly yellowish powder

Odour: Odourless

Solubility: Practically insoluble in cold water and in ethanol (95%)

pH: 4.5 to 7.0

Melting Point: 185 °C

Identification:

Heat to boiling for 1 minute a suspension of 1 gram in 50ml of water and cool; a thin and cloudy of mucilage is produced.

Iodine test: 10ml of above mucilage solution add 0.05 of 0.01ml iodine; a dark blue colour is produced.

Storage & Preservation:

To be stored on above ground, on clean dry and dust free storage area. Maintain ambient temperature and Keep away from water, direct sunlight and flames.[30]

MICROCRYSTALLINE CELLULOSE:-

Nonproprietary Name:

Microcrystalline cellulose, Cellulosum microcrystallinum.

Synonyms:

Avicel PH, celex, cellulose gel, hellulosum microcrystallinum, Emcocel, Fibrocel, Pharmacel, Vivace, E460.

Empirical formula:

$(C_6H_{10}O_5)n$, where n=220

Molecular weight:

Approx.36000

Solubility:

Practically insoluble in water, in acetone, in ethanol, in toluene, in dilute acids and slightly soluble in a 5.0 percent w/v solution of sodium hydroxide.

pH:

5.0-7.5

Identification test:

To about 1 mg add 1 ml of phosphoric acid, heat on a water bath for 30 minutes, add 4ml of a 0.2% w/v solution of catechol in phosphoric acid and heat for further 30 minutes; a red colour is produced.

Applications:

It is used primarily as a binder/diluent in oral tablet and capsule formulations where it is used in both wet granulation and direct

compression processes. It also has some lubricant, anti-adherent, and disintegrating properties, which make it useful in tablets.

Description:

Microcrystalline cellulose is purified, partially depolymerized cellulose that occurs as white, odourless, tasteless, crystalline, crystalline powder composed of porous particles. It is commercially available in various particle sizes and moisture grades that have different properties and applications.

Typical properties:

pH-5.0 to 7.5

Density (true) –

1.512 to 1.668 g/cm^3

Melting point –

Chars at 260 to 270^{o}C

Moisture content –

<5% w/w; hygroscopic

Incompatibilities:

Incompatible with strong oxidizing agents.

Safety:

Microcrystalline cellulose is widely used in oral pharmaceutical formulations and food products and is generally regarded as a relatively nontoxic and non-irritant material. Microcrystalline cellulose is not absorbed systemically following oral administration and thus has little

toxic potential. Consumption of large quantities of cellulose may have a laxative effect, although this is unlikely to be a problem when cellulose is used as an excipient in pharmaceutical formulations. Deliberate abuse of formulations containing cellulose, either by inhalation or by injection, has resulted in the formation of cellulose granulomas.[32]

SODIUM METHYLPARABEN (MPS):-

Sodium Methylparaben is the sodium salt of methyl 4-hydroxybenzoate. Sodium Methylparaben contains not less than 99.0 per cent and not more than 102.0 per cent of $C_8H_7NaO_3$, calculated on the anhydrous basis.

Synonyms:

Sodium Methyl hydroxyl benzoate

Molecular formula:

$C_8H_7NaO_3$

Molecular weight:

Mol. Wt. 174.1

Description:

A white, crystalline powder; odourless or almost odourless, hygroscopic.

Solubility:

Freely soluble in water; sparingly soluble in ethanol (95%), practically insoluble in fixed oils.

pH:

9.5-10.5

Category:

Pharmaceutical aid (anti-microbial preservative)

Identification:

Dissolve 0.5 g in 5 ml of water and acidify to litmus paper with hydrochloric acid; a white precipitate is produced. Wash the precipitatewith water and dry.

Storage:

Store protected from moisture.[32]

SODIUMPROPLYPARABEN (PPS):-

Sodium Propylparaben is the sodium salt of propyl 4-hydroxybenzoate. Sodium Propylparaben contains not less than 99.0 per cent and not more than 102.0 per cent of $C_{10}H_{11}NaO_3$, calculated on the anhydrous basis.

Synonyms:

Sodium propyl hydroxybenzoate

Molecular formula:

$C_{10}H_{11}NaO_3$

Molecular weight:

Mol. Wt. 202.2

Description:

A white, crystalline powder; odourless or almost odourless, hygroscopic.

Solubility:

Freely soluble in water and in ethanol (50%); sparingly soluble in ethanol (95%), practically insoluble in fixed oils.

pH:

9.5-10.5

Category:

Pharmaceutical aid (anti-microbial preservative)

Identification:

Dissolve 0.5 g in 5 ml of water and acidify to litmus paper with hydrochloric acid; a white precipitate is produced. Wash the precipitate with water and dry.

Storage:

Store protected from moisture.[33]

POLYVINYLPYRROLIDONE (PVP):-

Molecular Formula:

(-CH (NCH2CH2CH2CO) CH2-) n

Non-proprietary Names:

Povidone (BP, JP, PhEur, USP)

Synonyms:

Kollidon,Poly [1-(2-oxo-1-pyrrolidinyl) ethylene], polyvidone, Polyvinylpyrrolidone, povidonum, Povipharm, PVP, 1-vinyl-2-pyrrolidinone polymer.

Molecular weight:

35,000-51,000

Description:

Povidone occurs as a fine, white to creamy white coloured, odourless or almost odourless, hygroscopic powder.

Solubility:

Freely soluble in acids, chloroform, ethanol (95%), ketones, methanol and water. Practically insoluble in ether, hydrocarbon and mineral oil.

Functional category:

Disintegrant, dissolution enhancer, suspending agent and tablet binder.

Applications:

In tableting, povidone solutions are used as binders in wet-granulation processes. It is used as a solubilizer in oral and parenteral formulations and has been shown to enhance dissolution of poorly soluble drugs from solid-dosage forms.

Povidone solutions may also be used as coating agents or as binders. Additionally it is used as a suspending agent, stabilizing or viscosity-increasing agent in a number of topical, oral suspensions and solutions.

The solubility of a number of poorly soluble active drugs may be increased by mixing with povidone.

Incompatibilities:

It forms molecular adducts in solution with sulfathiazole, sodium salicylate, salicylic acid, Phenobarbital, tannin and other compounds.[37]

TALC:-

Non-proprietary names:

Purified talc, Talc, Talcum

Synonyms:

Magsil star, powdered talc, hydrous magnesium calcium silicate, hydrous magnesium silicate, purified French chalk, Purtalc, and soapstone.

Chemical name:

Talc

Molecular formula:

$Mg_6(Si_2O_5)_4(OH)_4$

Description:

Talc is a very fine, white to grayish-white, odourless, impalpable, unctuous, crystalline powder. It adheres readily to the skin and is soft to the touch and free from grittiness.

Functional Category:

Anticaking agent, glidant, tablet and capsule diluents, tablet and capsule lubricant.

Typical properties:

pH:

7-10

Moisture content:

Talc absorbs insignificant of water at 25°C and relative humidity's up to about 90%.

Solubility:

Practically insoluble in dilute acids and alkalis, organic solvents, and water.

Applications:

Talc was once widely used in oral solid dosage formulations as a lubricant and diluents. However, it is widely used as a dissolution retardant in the development of controlled-release products.

Talc is also used as a lubricant in tablet formulation.

In a novel powder coating for extended-release pellets and as an adsorbent.

In topical preparation, is used as a dusting powder.

Incompatibilities:

Incompatible with quaternary ammonium compounds.

Stability:

Talc is a stable material and may be sterilized by heating at 160°C for not less than 1hour. It may also be sterilized by exposure to ethylene oxide or gamma irradiation. Talc should be stored in a well-closed container in a cool, dry place.

Storage:

Store protected from moisture.[37]

MAGNESIUM STEARATE:-

Synonyms:

Magnesium octadecanoate, octadecanoic acid, Magnesium salt and stearic acid.

Chemical Name:

Octadecanoic acid magnesium salt.

Description:

It occurs as a fine, white precipitated or milled impalpable powder with a faint odour and a characteristic taste.

Functional categories:

Tablet and capsules lubricant.

Molecular formula:

$C_{36}H_{70}MgO_4$

Molecular weight:

591.34

Typical properties:

Density (bulk):0.159g/cm3

Density (tapped):

0.286g/cm3

Melting point:

88.5°C

Solubility:

Practically insoluble in ethanol, ether and water, slightly soluble in warm benzene and warm ethanol (95%).

Melting point:

117-150°C

Stability and storage Conditions:

It is stable and should be stored in a well-closed container in a cool, dry place.

Incompatibilities:

Incompatible with strong acids, alkalis and iron salts.

Applications:

It is primarily used as a lubricant in tablet and capsules in concentration between 0.25% and 5%. It is widely used in cosmetic and food industry.

Safety:

It is widely used as a pharmaceutical excipient and is generally regarded being nontoxic following oral administration. However, oral consumption of large quantities may result in some laxative effect or mucosal irritation. Inhalation of magnesium stearate powder is harmful and has resulted in fatalities.[33,37,40]

AIM & OBJECTIVE

AIM:

The aim of the study is to extract a polysaccharide from the fruit of the *Solanum betaceum Cav* and to study the characteristic of the polysaccharide as a binding agent in the formulation of tablets.

OBJECTIVE:

- To isolate polysaccharide from *Solanum betaceum cav* fruit,
- To evaluate its physicochemical properties of the polysaccharide
- To formulate and evaluate paracetamol tablet using above polysaccharide.

PLAN OF WORK

PLAN OF WORK:

- Collection and authentication of the *Solanum betaceum cav*
- Isolation of polysaccharide from the *Solanum betaceum cav*
- Physiochemical characterization of polysaccharide
- Cytotoxicity studies
- Preformulation studies
  - Calibration curve using UV-Visible spectroscopy
  - Compatability studies using
    - FT-IR spectroscopy
    - DSC Thermal analysis
    - XRD analysis
- Formulation of matrix tablet
  - Wet granulation method
  - Precommpression study of tablet blend
    - Bulk density
    - Tapped density
    - Compressibility index
    - Hausners ratio
    - Angle of repose
- Evaluation of Tablets
    - Hardness
    - Weight variation
    - Friability
    - Thickness and diameter
    - Uniformity of content
    - In vitro dissolution studies
    - Statistical analysis

MATERIALS

&

METHODS

METERIALS AND METHODS

Extraction, Isolation and Characterization of Mucilage:

MATERIALS

Table: 1 List of chemicals used and manufacturers:

S.NO	CHEMICALS	SOURCE
1	Acetone	Nice chemicals pvt ltd, India

Table: 2 List of instruments used and manufacturers:

S.NO	INSTRUMENTS	MAKE
1	Digital pH meter	Deluxe pH meter 103
2	Centrifuge	Remi motors, India
3	Mechanical shaker	Genuine
4	Digital weighing balance	Shimadzu corporation, AY 120, Japan
5	Bulk density apparatus	Sri Mahalakshmi Scientific Co., Coimbatore
6	FT-IR	Shimadzu FT-IR 8400S, Japan
7	X-ray diffraction	Siemens D5000 X-ray diffractometer (Siemens, Munich, Germany)
8	DSC	DSC Q200 V24.4 Build 115

COLLECTION AND AUTHENTIFICATION

The plant fruits were collected from Ooty. It is identified as *Solanum betaceum cav* and a specimen is deposited in **Botanical Survey of India, Southern Regional Centre, Tamilnadu Agricultural University Campus, Coimbatore.**

METHODS:

Extraction of Mucilage:

The fresh fruits of *Solanum betaceum cav* was collected from ooty hills station.The fruits are cut in to small pieces and then it is soaked in a beaker containing distilled water.The fruits are homogenized for 2 hours in water. Then the solution was mixed using magnetic stirrer for 30 minutes and kept 1 hour for complete release of mucilage into water. The solution was squeezed and filtered by using muslin bag.

Isolation of Polysaccharide:

The filtrate was collected and the mucilage was precipitated with three times its volume of acetone. The precipitate was obtained, and further washed three times by acetone. The light brown colour solid was dried under vacuum for 60 hours. Finally isolated polysaccharide was powdered passed through sieve number 80 and stored in desiccators for use in subsequent tests. The yield was found to be 6.4 g mucilage/500g of fruits.[46,53]

Physicochemical Characterization:

Table: 3 Identification Test of Mucilage

Test	Experiment	Observation
Molisch's Test	(100mg dried mucilage powder + Molisch's reagent + conc.H_2SO_4 on the side of a test tube)	Violet green colour observed at the junction of the two layers
Ruthenium Test	Take a small quantity of dried mucilage powder, mount it on a slide with ruthenium red solution, and observe it under microscope.	Pink colour develops
Iodine Test	100mg dried mucilage powder + 1 ml 0.2N iodine solution.	No colour observed in solution

Organoleptic Evaluation:

The isolated mucilage was subjected for various organoleptic evaluations which included evaluation of colour, odour, shape, taste and special features like touch and texture. The majority of information on the identification, purity and quality of the material can be drawn from these observations.

Solubility test:

The separated mucilage was evaluated for solubility in water, acetone, chloroform, methanol, ether and ethanol in accordance with the Indian Pharmacopoeia specifications.

Loss on drying:

Loss on drying (LOD) is used to determine high levels of moisture or solvents present in the sample. 1.0 g of the sample powder was weighed and transferred into petri dish and then dried in an oven at 105°C for 2 hrs a constant weight was obtained. The sample was cooled in the dry atmosphere of a desiccator, and then reweighed. The percentage loss of moisture on drying was calculated using the formula and expressed as a percentage.

LOD(%) = (Weight of water in sample / Weight of dry sample) × 100

Swelling index:

Swelling index of *Solanum betaceum cav* mucilage powder was determined by accurately weighed 1 g of mucilage powder was transferred into a 25ml glass Stoppard measuring cylinder. The initial bulk volume was noted. Then 25ml of water was added and mixture was shaken thoroughly every 10 min for 1 h. It was then allowed to stand for 3h at room temperature. Then the volume occupied by mucilage, was measured. The same procedure was repeated thrice and the mean value was calculated.

Swelling index (SI) is expressed as a percentage and calculated according to the following equation.

Swelling index (SI) =V_2-$V_1$$V_1$× 100

Where: $V_1$is initial volume of powder before hydration.

V_2 is volume of swollen powder after (3 hours) hydration.

Bulk density:

The accurately weighed powder was introduced into a 100ml graduated cylinder and the volume was noted. The bulk density was calculated using the formula:

Bulk density (ρ) = Mass of powder (w) / Bulk volume (V_b)

Tapped density:

The accurately weighed powder was introduced into a 100ml graduated cylinder. The cylinder was fixed on to the Tap density Apparatus (Sri Mahalakshmi Scientific Co., Covai) and the timer knob was set for 100 tappings. The volume occupied by the powder was noted. After 100 tapping's the final volume was noted. The tap density was calculated using the formula:

Tap density = Mass of powder (w) / Tap volume (V_t)

Compressibility index (C %) (Carr's index):

The difference between the tapped and bulk density divided by the tapped density was calculated and ratio expressed as a percentage.[82]

Carr's Index = Tap density – Bulk density / Tap density × 100

Hausner's ratio:

It is the ratio of tapped density to Bulk density of the powder. The ratio gives an insight to the degree of densification of powders which could occur during tableting.

Hausner's ratio = Tap density / Bulk density

Angle of repose:

A glass funnel was placed 2 cm above the horizontal plane using a clamp. The sample of 5 g was transferred into funnel keeping the orifice of the funnel blocked by thumb. Then the thumb was removed and the powder was allowed to flow. When the powder was emptied from

the funnel, the height (h) of the pile and radius (r) of the base was measured. The angle of repose was calculated using the formula.

$$\tan \theta = h/r$$

$$\text{hence, } \theta = \tan^{-1} h/r$$

Where,

θ = angle of repose

h = height of pile

r = radius of pile

pH determination:

The mucilage was weighed and dissolved in water separately to get a 1%w/v solution. The solution was shaken for 5 min. The pH of solution was determined using digital pH meter.

Ash values:

Ash values such as total ash, acid insoluble ash and water soluble ash were determined according to Indian Pharmacopoeia. The following procedures were used for determination of ash values.

a) Total Ash:

About 3 g of sample was accurately weighed and taken in a silica crucible, which was previously ignited and weighed. The powder was spread as a fine, even layer on the bottom of the crucible. The crucible was incinerated gradually by increasing temperature to make it dull red hot until free from carbon. The crucible was cooled and weighed. The procedure was repeated to get constant

weight. The percentage of total ash was calculated with reference to air dried sample.

b) Acid Insoluble Ash:

The ash obtained as described above was boiled with 25ml of 2N HCL for five minutes. The insoluble ash was collected on an ash less filter paper and washed with hot water. The insoluble ash was transferred into a silica crucible, ignited and weighed. The procedure was repeated to get a constant weight. The percentage of acid insoluble ash was calculated with reference to the air-dried sample.

c) Water soluble Ash:

The ash obtained as described for the determination of total ash was boiled for 5 min with 25 ml of water. The insoluble matter was collected on ash less filter paper and washed with hot water. The insoluble ash was then transferred into silica crucible, ignited for 15 min, and weighed. The procedure was repeated to get a constant weight. The weight of insoluble matter was subtracted from the weight of the total ash. The difference of weight was considered as water-soluble ash. The percentage of water-soluble ash was calculated with reference to the air dried sample.

Viscosity determination:

Rheological studies of dried mucilage were carried out using concentration (1% w/v) prepared in distilled water. The viscosities were measured using an Oswald's viscometer.[58,63,68]

Drug – Excipient Compatibility studies:

Physical mixture of drug and mucilage were filled in the prewashed, dried plastic container and sealed. The sealed container was stored at 37°C±0.5°C for 28 days in stability chamber. At the end of 28 days plastic container were removed from stability chamber and subjected for interaction of drug-excipient compatibility studies. Drug – Mucilage interaction study was carried out by thermal and FTIR analysis.

Thermal analysis:

Thermal properties of melting point of *solanum betaceum cav* mucilage and drug and physical mixture of mucilage and drug powder 1:1 ratio was characterized by using DSC, (SDT Q600 V20.9 Build 20). The powdered material were sealed in aluminium pan and heated from 10.00 °C/min to 400.00 °C/min. The decomposed melting temperature was measured and observed.[80]

FTIR analysis:

Pure drug sample, isolated mucilage powder of *solanum betaceum cav* and the physical mixture of drug with excipient in the ratio 1:1 were subjected to IR spectral studies using FTIR spectrophotometer. A physical mixture of drug and isolated mucilage was mixed with desirable quantity of potassium bromide. 100 mg of this mixture was compressed to form a transparent pellet using hydraulic press at 15 tons pressure. It was scanned from 4000-400 cm^{-1} in a FTIR – 8400 Shimadzu, JAPAN. The individual spectra of the drug and mucilage were performed.[81]

X-ray powder diffraction study:

X-ray diffraction (XRD) patterns of the mucilage powder were analyzed using a Siemens D5000 X-ray diffractometer (Siemens, Munich, Germany). Powder sample, packed in rectangular aluminium cell radiation (ʎ = 1.54056 A°) were scanned between diffraction angles of 5° to 45°C. The scan speed was measured 10.0000(deg/min). Scan steps of 0.100 (deg) were

0.60 Sec. A nickel filter was used to red contribution to the X-ray signal. The 'd' spacing was computed according to Bragg's law of diffraction. Triplicate measurements were made at ambient temperature.[81]

Toxicity (cytotoxicity) studies:

Cell line:

The human embryonic kidney cell line (HEK 293) was obtained from National Centre for Cell Science (NCCS), Pune and grown in Eagles Minimum Essential Medium containing 10% fetal bovine serum (FBS). The cells were maintained at 37^0C, 5% CO2, 95% air and 100% relative humidity. Maintenance cultures were passaged weekly, and the culture medium was changed twice a week.

Cell treatment procedure:

The monolayer cells were detached with trypsin-ethylenediaminetetraacetic acid (EDTA) to make single cell suspensions. The viable cells were counted using hemocytometer by tryphan blue exclusion method and diluted with medium containing 5% FBS to give final density of $1x10^5$ cells/ml. One hundred microlitres per well of cell suspension were seeded into 96-well plates at plating density of 10,000 cells/well and incubated to allow for cell attachment at 37^0C, 5% CO_2, 95% air and 100% relative humidity. After 24 h the cells were treated with serial concentrations of the test samples. They were initially dissolved in phosphate buffered saline (PBS) by sonication and an aliquot of the sample solution was diluted to twice the desired final maximum test concentration with serum free medium. Additional four serial dilutions were made to provide a total of five sample concentrations. Aliquots of 100 µl of these different sample dilutions were added to the appropriate wells already containing 100 µl of medium, resulting in the required final sample concentrations. Following sample addition, the plates were incubated for an additional 24 h at 37^0C, 5% CO_2, 95% air and 100% relative humidity. The medium containing without samples were served as control and triplicate was maintained for all concentrations.

MTT assay:

3-[4,5-dimethylthiazol-2-yl]2,5-diphenyltetrazolium bromide (MTT) is a yellow water soluble tetrazolium salt. A mitochondrial enzyme in living cells, succinate-dehydrogenase, cleaves the tetrazolium ring, converting the MTT to an insoluble purple formazan. Therefore,the amount of formazan produced is directly proportional to the number of viable cells.

After 48 h of incubation, 15µl of MTT (5mg/ml) in phosphate buffered saline (PBS) was added to each well and incubated at 37^0C for 4h. The medium with MTT was then flicked off and the formed formazan crystals were solubilized in 100µl of DMSO and then measured the absorbance at 570 nm using micro plate reader.

The percentage cell growth was then calculated with respect to control as follows:

% Cell Growth = [A] Test / [A]control x 100

FORMULATION AND DEVELOPMENT

MATERIALS:

Table: 4 List of chemicals used and manufacturers:

S.NO	CHEMICALS	SOURCE
1	Paracetamol	Granules India
2	Starch	Ridhi Siddhi
3	Microcrystalline Cellulose powder	Loba chemie Pvt Ltd., Mumbai, India
4	Polyvinylpyrrolidone	J.B.Khokhani & co, Mumbai
5	Sodium Methylparaben	Nebula health care
6	Sodium Propylparaben	Nebula health care
7	Talc	Suprime Traders
8	Magnesium Stearate	Pantogan

All above materials were obtained as gift sample from Kreszent Pharma, Pondicherry and Karpagam pharma LLP, Coimbatore.

Table: 5 List of instruments used and manufacturers:

S.NO	INSTRUMENTS	MAKE
1	Hot air oven	Technico
2	Digital weighing balance	Shimadzu corporation, AY 120, Japan
3	UV Spectrophotometer	Cyberlab UV-100
4	Tabletpunching machine	Shakti Pharmatech Pvt Ltd
5	Vernier calipers	Mahr Instruments, Ahmadabad
6	Disintegrating test apparatus	Deep vision
7	Dissolution test apparatus	Lab india-DS 8000
8	Monsanto hardness tester	Dolphin
9	Friability test apparatus	Dolphin CAI No 1015-C
10	Desiccator	Tarson

FORMULATIONS:

Table: 6 Composition of paracetamol tablets using *Solanum betaceum cav* polysaccride, *Starch* and *PVP* as Binding Agents:

FORMULA ➡ / INGREDIENTS ⬇	F1 (4%)	F2 (6%)	F3 (8%)	F4 (4%)	F5 (6%)	F6 (8%)	F7 (4%)	F8 (6%)	F9 (8%)
Paracetamol	250	250	250	250	250	250	250	250	250
Starch	80.8	76.8	72.8	80.8	76.8	72.8	80.8	76.8	72.8
Microcrystalline Cellulose	40	36	32	40	36	32	40	36	32
Solanum betaceum cav mucilage (Binder)	**16**	**24**	**32**	-	-	-	-	-	-
Starch (Binder)	-	-	-	**16**	**24**	**32**	-	-	-
Polyvinylpyrrolidone (Binder)	-	-	-	-	-	-	**16**	**24**	**32**
Sodium Methylparaben	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Sodium Propylparaben	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Demineralized water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Talc	8	8	8	8	8	8	8	8	8
Magnesium Stearate	4	4	4	4	4	4	4	4	4
Total weight	400	400	400	400	400	400	400	400	400

All the above ingredients quantities are mg / tablet.

METHODS

Preparation of Paracetamol Granules by Wet Granulation Method:

Different batches of granules were prepared by wet granulation technique by following procedure

Procedure:

- Drug and excipients were weighed accurately and separately in weighing balance.
- Then **drug** passed through **sieve no: 40** and **excipients** were passed through **sieve no: 60**.
- Then drug and excipients materials were placed in a transparent plastic container and **mixed for 5 minutes**.
- **Binder solution** was prepared by using **demineralized water** with addition of **preservative agent**.
- Powder blend was granulated with binding solution by slow addition in **glass mortar** by kneading method (**hand granulation**).
- Then obtained wet mass was **dried at 30°C** in hot air oven until half wet mass for **3 minutes**.
- Then granules were passed through **sieve no: 36** and again **dried at 30°C** for **3 minutes.**
- Then the dried granules were passed through sieve no: 36 and collected granules were weighed.
- To the dried granules, **disintegrating agent** (if applicable formulation) was added externally and mixed well in a plastic container for **1 minute.**
- Then **talc, magnesium stearate**, as lubricants were added and mixed well in a plastic container for **1 minute**.
- The granules were **stored** in plastic containers for further **evaluation** and **compressed into tablets.**[69,77]

Evaluation of Granules Properties:

The flow properties of granules were determined by following methods

- **Bulk density:**

The accurately weighed granules were introduced into a 100ml graduated cylinder and the volume was noted. The bulk density was calculated using the formula:

$$\text{Bulk density } (\rho) = \frac{\text{Mass of granules (w)}}{\text{Bulk volume } (V_b)}$$

- **Tap density:**

The accurately weighed granules were introduced into a 100ml graduated cylinder. The cylinder was fixed on to the Tap Density Apparatus (Sri Mahaalakshmi scientific co) and the timer knob was set for 100 tapping. The volumes occupied by the granules were noted. After 100 tapping's the final volume was noted. The tap density was calculated using the formula:

$$\text{Tap density} = \frac{\text{Mass of granules (w)}}{\text{Tap volume } (V_t)}$$

- **Compressibility index (C %) (Carr's index):**

The difference between the tapped and bulk density divided by the tapped density was calculated and ratio expressed as a percentage.

$$\text{Carr's Index} = \frac{\text{Tap density} - \text{Bulk density}}{\text{Tap density}} \times 100$$

- **Hausner's ratio:**

It is the ratio of tapped density to Bulk density of the granules. The ratio gives an insight to the degree of densification of granules which could occur during tableting.

Hausner's ratio = Tap density / Bulk density

- **Angle of repose:**

A glass funnel was placed 2 cm above the horizontal plane using a clamp. The sample of 5 g granules were transferred into funnel keeping the orifice of the funnel blocked by the thumb. Then the thumb was removed and the powder was allowed to flow. When the powder was emptied from the funnel, the height (h) of the pile and radius (r) of the base was measured. The angle of repose was calculated using the formula:

$$\theta = \tan^{-1} h/r$$

Compression of Tablets:

The different batch of granules were produced and compressed into an average weight of 400mg per tablet using rotary punch tablet compression machine (Shakti Pharma tech Pvt Ltd.) fitted with a concave punch and die set.

Evaluation of Tablets:

- **Weight Variation:**

Randomly twenty tablets per batch were selected after compression and the mean weight was determined. The sample tablets were weighed individually and the deviation from the mean weight was calculated.

- **Hardness:**

The crushing strength of the tablets were measured using a Monsanto hardness tester. Six tablets from each formulation batch were tested randomly and the average reading was noted.

- **Thickness and diameter*:***

The thickness and diameter of the matrix tablets of all batches were determined using Vernier caliper and the results were expressed as mean values of 10 determinations, with standard deviations.

- **Friability test:**

Randomly 20 tablets per batch were selected after compression and friability of the tablets were determined using Friability Tester rotated at 25rpm for 4 minutes. The tablets were taken out, dedusted and reweighed. The loss in weight expressed as a percentage of the original weight of the tablets represented the friability. Percentage friability was determined by following formula.

$$\textbf{Percentage friability} = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\textbf{Initial weight}} \times 100$$

- **Disintegration test:**

In vitro disintegration time was measured by disintegration tester. The tablet was placed in each of six tubes in 1000ml beaker containing water maintained the temperature at 37°C ± 2°. The time taken for the tablet to disintegrate completely was noted by using stop watch.

- **Assay of paracetamol:**

Assay of all the formulations were carried out as per IP. Twenty tablets were weighed and powdered. An amount of the powder equivalent to 150mg of Paracetamol was dissolved in 50 ml of *0.1 M sodium hydroxide*, diluted with 100 ml of *water*, shaked for 15 minutes and added sufficient *water* to produce 200.0 ml and mixed well and Filtered. Diluted 10.0 ml of the filtrate to 100.0 ml with *water*. To 10.0 ml of the resulting solution, 10 ml of *0.1 M sodium hydroxide* was added and diluted to 100.0 ml with *water* and mixed well. The absorbance of the resulting solution was measured at 257 nm using

UV -Visible spectrophotometer (UV PROBE).and calculated the content of paracetamol taking 715 as the specific absorbance at 257 nm.

- **Dissolution studies:**

Calibration Curve of Paracetamol

Preparation of Stock Solution:

- Accurately weighed 100 mg of the pure drug of paracetamol was transferred to 100 ml volumetric flask. The drug was dissolved in phosphate buffer pH 5.8. Then the volume was made up to 100 ml mark (stock solution I of 1000 µg/ml was made).
- 10 ml of the above solution was pipette out into a 100 ml volumetric flask. Then the volume was made up to 100 ml using phosphate buffer pH 5.8 (stock solution II of 100 µg/ml was made).
- Then 2, 4, 6, 8, 10, and 12 ml of the above stock solution II was pipette out into separated volumetric flask. Then the volume was made up to 100 ml using phosphate buffer pH 5.8.
- The absorbance's of the above solutions were measured at 243nm and calculated.

Method of dissolution:

In vitro drug release studies of all the formulations were carried out using USP type- II tablet dissolution test apparatus as per IP. At first 900 ml of dissolution medium of *phosphate buffer pH 5.8* was placed in basket container with temperature maintained at 37±2ºC. Then the tablet was introduced into the basket container and paddle was rotated at 50 rpm up to 30 minutes. 2 ml Sample solution was withdrawn at 5, 10, 15, 20, 25, and 30 minutes time intervals from the basket container and again 2 ml of fresh dissolution medium was replaced into the basket container to maintain constant volume. The obtained sample solution was filtered by Whattman No.1 filter paper and diluted with 100 ml of *phosphate buffer pH 5.8* and mixed well. The absorbance of the resulting solution was measured at 243nm using UV -Visible spectrophotometer and calculated the percentage drug release of paracetamol.[79,80,81]

RESULTS

&

DISCUSSION

RESULTS AND DISCUSSION

Physicochemical characterization of isolated mucilage powder:

The physicochemical of *Solanum betaceum cav* mucilage were observed and the results were presented in table and. The identification tests of mucilage gave positive test for carbohydrate, mucilage in Molisch's and ruthenium tests respectively and the iodine test gave negative test for starch, thus polysaccharides is confirmed. The results were presented in table 7. Extracted and purified mucilage was evaluated for viscosity and pH. The pH of the mucilage was found to be 6.1. Since the pH value of this mucilage is near to neutral, it may be less irritating on gastrointestinal tract and hence was suitable for uncoated tablets. The flow properties of mucilage powder were determined by Carr's index, Hausner's ratio and angle of repose was found to be >23, >1.25, and 36^{o} - 40^{o} indicated poor and passable flow properties.

Table: 7 Preliminary Identification tests results for mucilage

S.No	Parameters	Observed	Results
1	Molisch's test	Violet green colour present at junction of two layers	Carbohydrate present
2	Ruthenium test	Pink colour developed	Mucilage present
3	Iodine test	No colour present in solution	Polysaccharides Present

Table: 8 Results of Physicochemical characterization of *Solanum betaceum cav* mucilage

Parameters	**Observed**
Organoleptic properties	Light green colour, amorphous nature, Mucilageous, odourless.
Solubility	Soluble in hot water, in cold water swell to form gel and practically insoluble in acetone, ethanol, chloroform and other organic solvents.
Loss on drying (%)	10.2%
Swelling index in distil water	55.1%
Bulk density	0.48±0.51 g/cm^3
Tapped density	0.53±0.056 g/cm^3
Carr's index	9.4±0.851
Hausner's ratio	1.1±0.046
Angle of repose (º)	23.0±1.26º
pH (1%w/v)	6.1
Total Ash (%)	1.24%
Water-soluble ash (%)	2.7%
Acid insoluble ash (%)	0.15%
Viscosity (1% w/v solution)	1.12 cps

Drug- Excipient Compatibility Studies:

Thermal analysis:

- **Differential scanning colorimetry (DSC):**

The figure shows the dsc spectra of paracetamol , polymer and 1:1 ratio of paracetamol and polymer. In DSC spectra of paracetamol is observed a sharp endotherm atits melting point. The DSC Spectra of the natural plant polymer shows a broad endotherm. In DSC thermal gram of 1:1 ratio(paracetamol:polymer) observed both sharp endotherm of Paracetamol and broad endotherm of plant polymer without any shift. This concludes that Paracetamol and *Solanum betaceum cav* are compatible for the formulation

Figure: 1 DSC of paracetamol

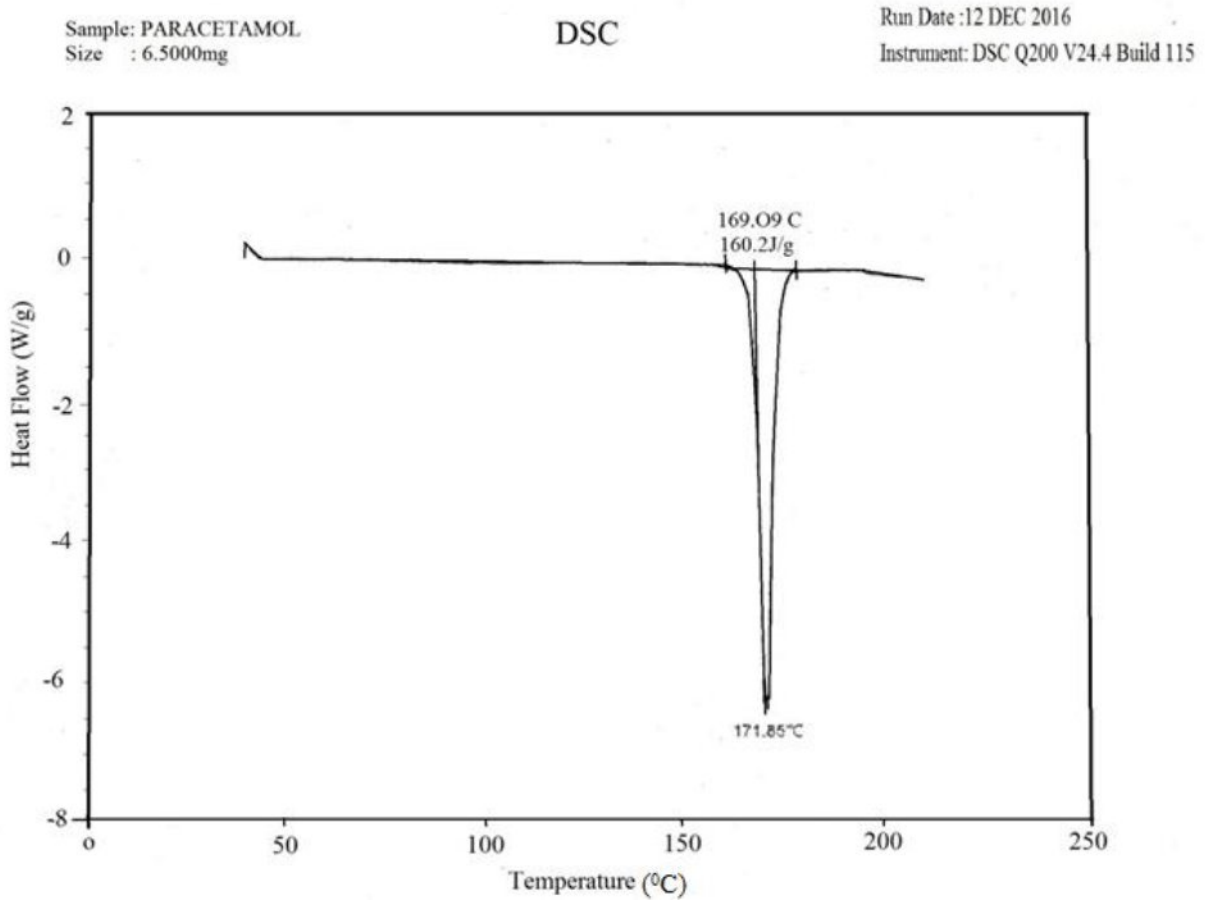


Figure: 2 DSC of *Solanum betaceum cav*

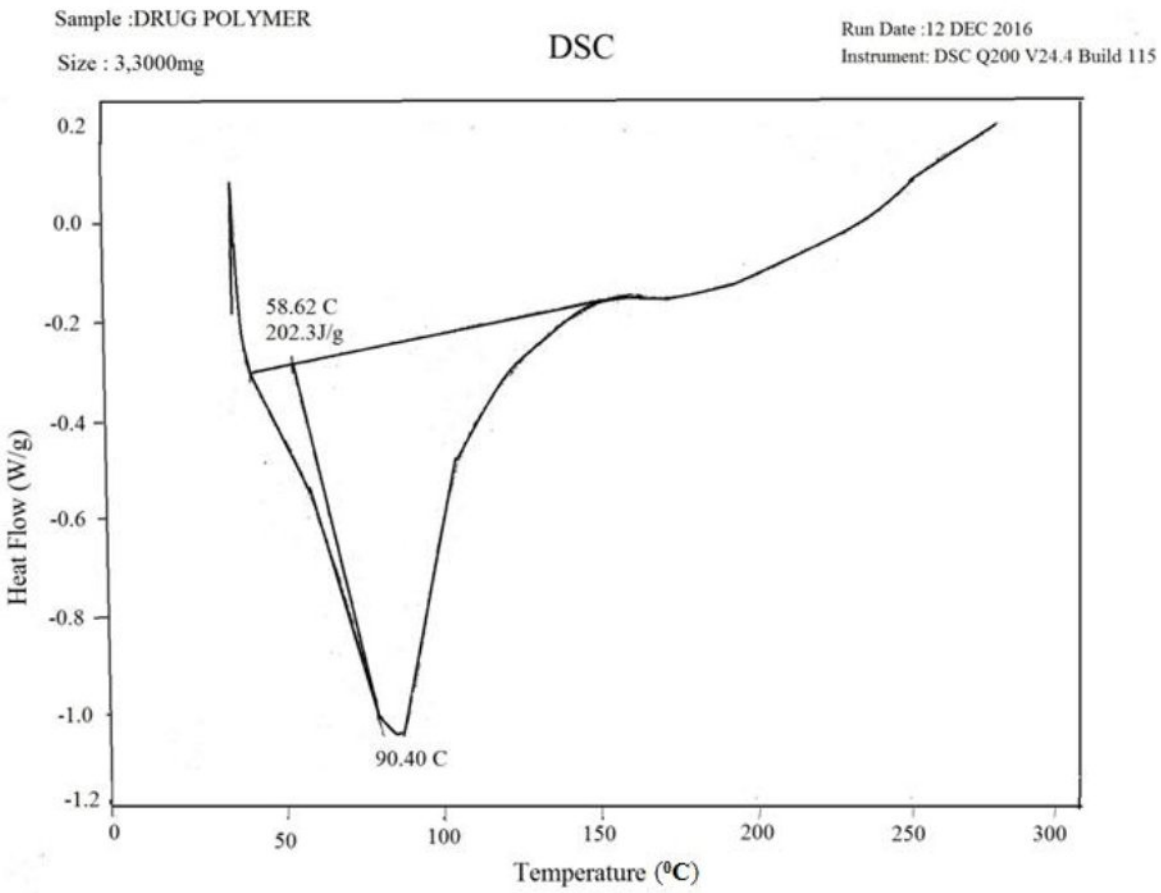
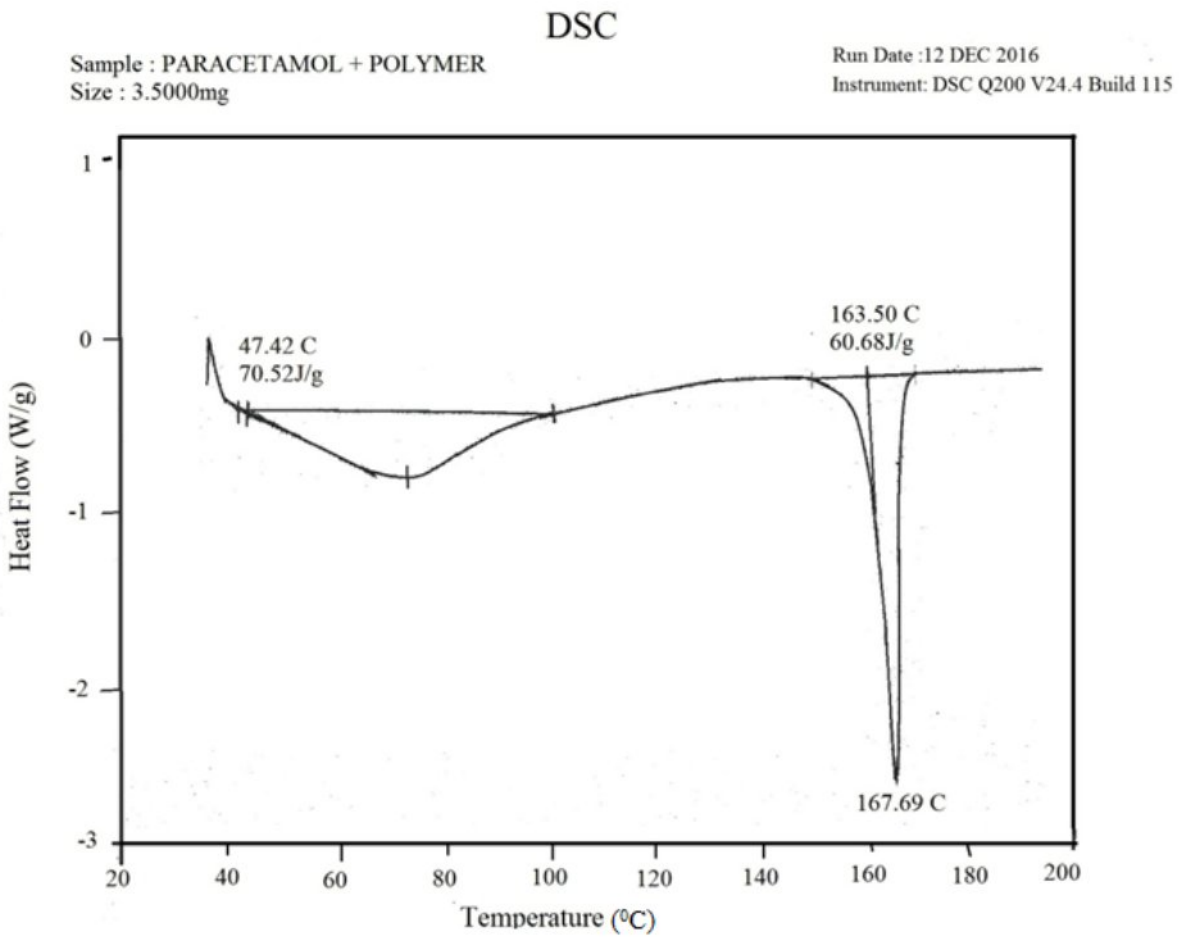


Figure: 3 DSC of paracetamol +*Solanum btaceum cav*



FTIR Analysis:

Figure: 4 FTIR Analysis of *Solanum betaceum cav*

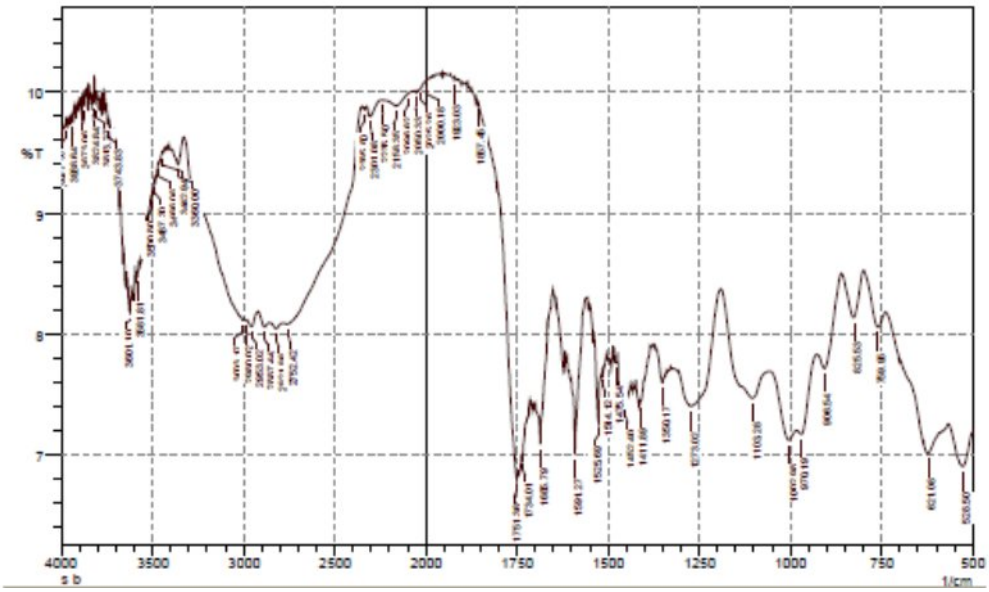


Figure: 5 FTIR Analysis of Paracetamol

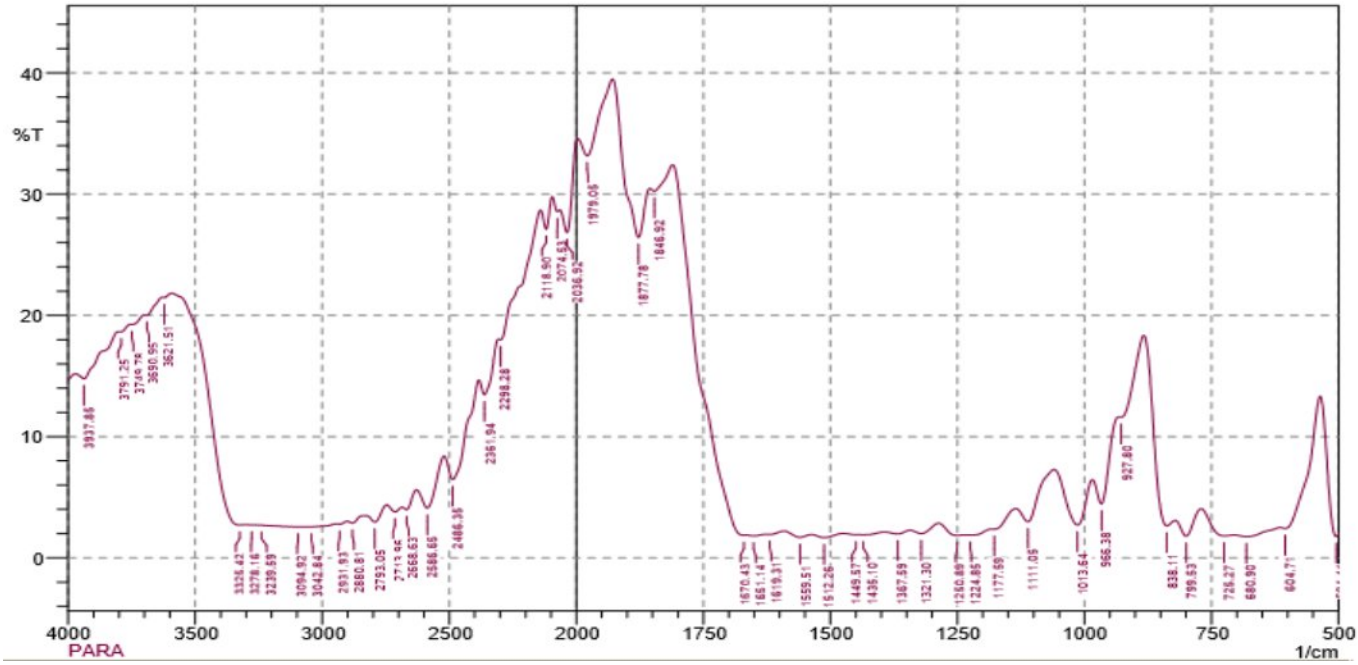


Figure: 6 FTIR of SB & Paracetamol

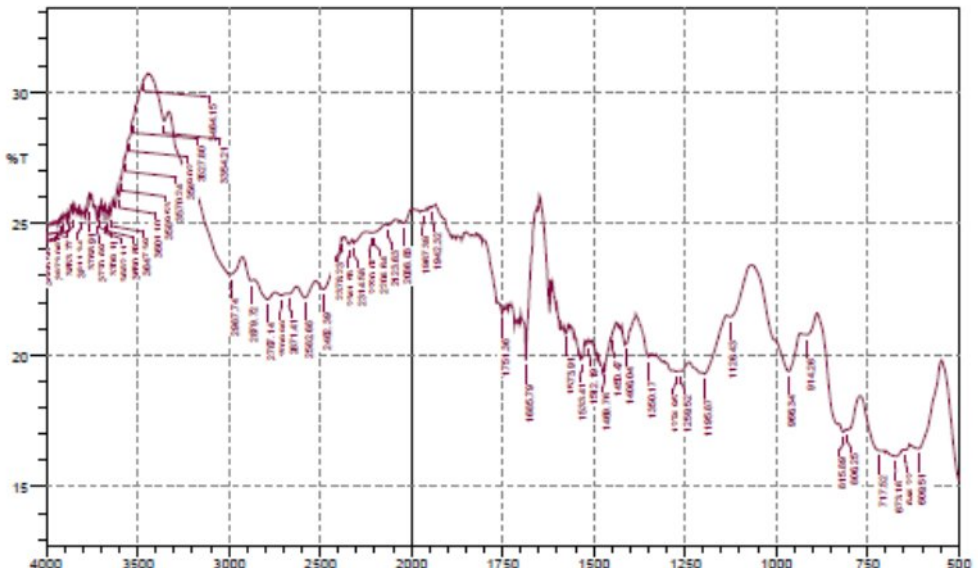
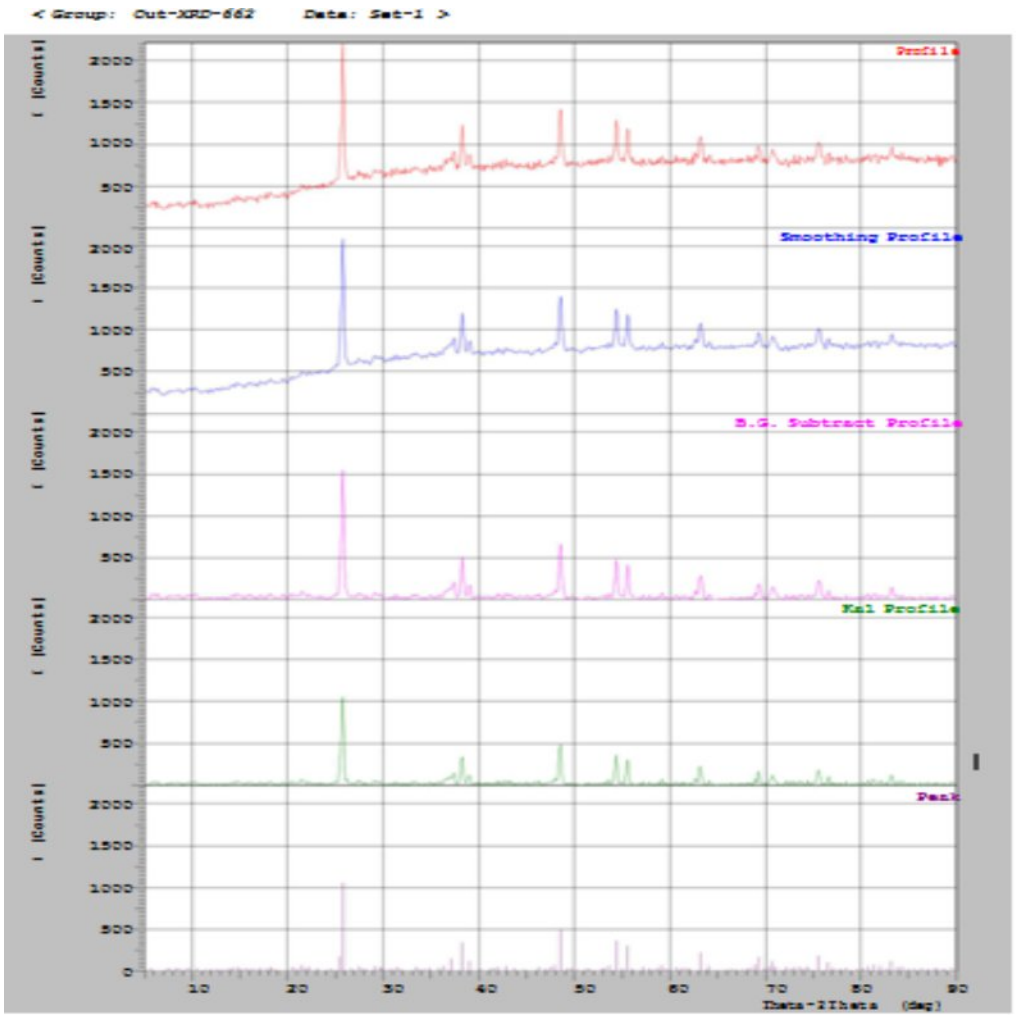


Table: 9 Interpretation of Solanum Betaceum Cav + Paracetamol

S.no	Observed peaks	Range (cm^{-1})	Characteristic group
1	806.25	860-680(s)	Aromatic C-H bending
2	1688.79	1690-1630(s)	Amide C=H stretch
3	3660.89	3700-3500(s)	Amide N=H stretch
4	3354.21	3550-3200(broad ,s)	Phenol O-H stretch
5	1685.75	1750-1680(s)	Ketone C=O stretch

X-ray powder diffraction study:

Figure: 7 XRD analysis of *Solanum betaceum cav* Mucilage



The surface morphology of mucilage powder was observed by XRD (X-ray diffraction method). The results were shown in Figure 7. By the spectra obtained by XRD, the mucilage powder of *Solanum betaceum cav* shows that the presence of numerous halos with weak peaks which indicate amorphous nature of material.

In vitro cytotoxicity study:

The toxicity study of *Solanum betaceum cav* polysacchride was performed in human embryonic kidney cell line. The cells were maintained at 37^0C, 5% CO_2, 95% air and 100% relative humidity. The concentration Vs absorbance and percentages of cell viability of test sample were calculated with control sample are presented in table 10 and 11 and figure 8 to 14. The human embryonic kidney cell line had no morphological changes and the cell viability was nearly (above 80%). Reduction of MTT by cells indicates mitochondrial activity, which may be interpreted as proof of cell viability. The SB was not induced cytotoxic effects at the used concentrations.

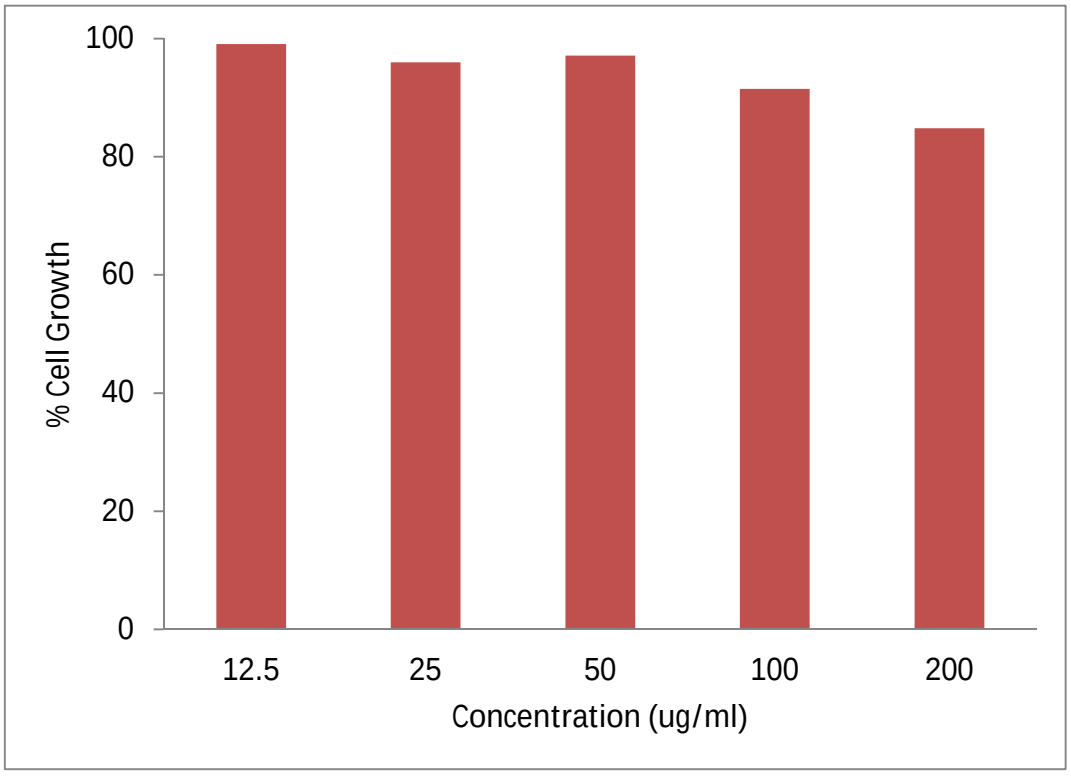
Table: 10 Concentration Vs absorbance of cell viability of test and control

Conc	**12.5 µg**	**25 µg**	**50 µg**	**100 µg**	**200 µg**	**Cont**
ABS	0.324	0.304	0.303	0.301	0.266	0.324
	0.318	0.306	0.314	0.289	0.274	0.322
	0.312	0.314	0.318	0.291	0.277	0.317
Avg	**0.318**	**0.308**	**0.311667**	**0.293667**	**0.272333**	**0.321**

Table: 11 Concentrations Vs % Cell Growth

Conc (µg/ml)	%Cell Growth
12.5	99.06542
25	95.95016
50	97.09242
100	91.48494
200	84.83904

Figure : 8 *invitro* cytotoxicity study



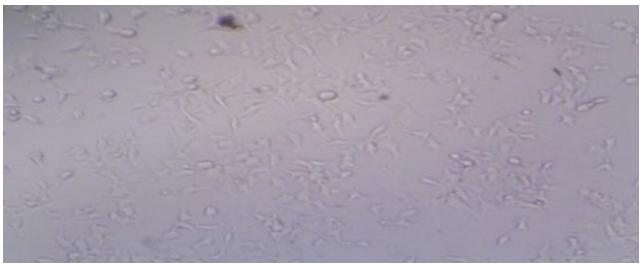
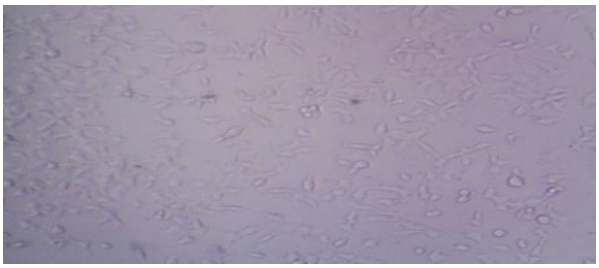
	

Figure: 9. Image of cytotoxicity in 12.5µg/ml	Figure: 10. Image of cytotoxicity in 25µg/ml

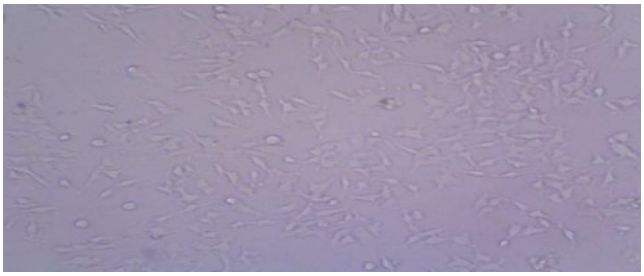
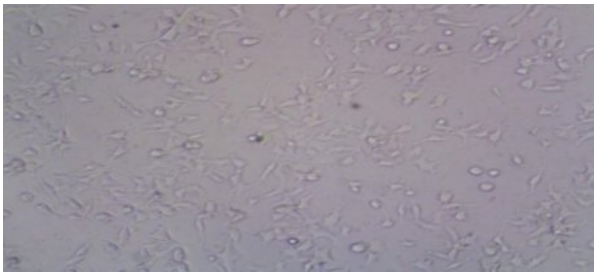

	

Figure: 11. Image of cytotoxicity in 50µg/ml	Figure: 12. Image of cytotoxicity in 100µg/ml

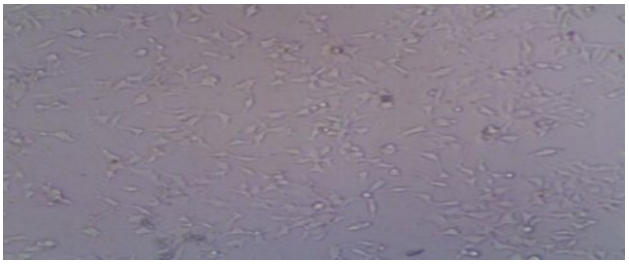
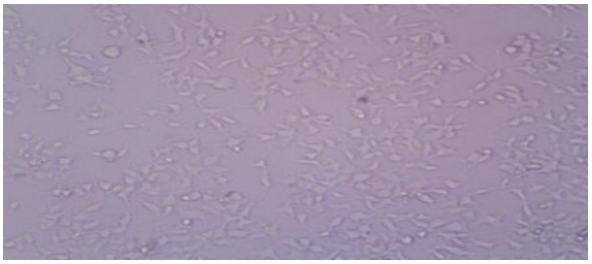

	

Figure: 13. Image of cytotoxicity in 200µg/ml	Figure: 14. Image of cytotoxicity of control sample

Evaluation of formulated granules:

The flow properties of prepared granules of different batches were determined and the results are presented in table 12. It was observed that the flow ability ranges were decreased when mucilage concentration (as binding agent) is increased. When compared with starch and PVP granules, the flow property of granules slightly differs. The Carr's index, Hausner's ratio and Angle of repose values of the granules made from the mucilage was found to be <23, <1.25 and 25° - 30° respectively. Hence all the granules exhibited excellent flow properties.

Table: 12 Flow properties of formulated granules

(Binding agents)

Binders →	**SB**			**STARCH**			**PVP**		
Formulations code → / **Parameters** ↓	**F1 (4%)**	**F2 (6%)**	**F3 (8%)**	**F4 (4%)**	**F5 (6%)**	**F6 (8%)**	**F7 (4%)**	**F8 (6%)**	**F9 (8%)**
Bulk density (g/ml)	0.315 ±0.00	0.319 ±0.00	0.326 ±0.00	0.434 ±0.00	0.442 ±0.00	0.446 ±0.00	0.438 ±0.00	0.446 ±0.00	0.442 ±0.00
Tapped density (g/ml)	0.356 ±0.00	0.357 ±0.00	0.359 ±0.00	0.526 ±0.00	0.500 ±0.00	0.490 ±0.00	0.505 ±0.00	0.490 ±0.00	0.480 ±0.00
Carr's index (%)	14.4 ±0.00	10.6 ±0.00	9.1 ±0.01	17.5 ±0.01	11.6 ±0.00	9.0 ±0.03	13.3 ±0.04	9.0 ±0.03	7.9 ±0.00
Hausner's ratio	1.13 ±0.00	1.11 ±0.00	1.2 ±0.01	1.21 ±0.00	1.13 ±0.00	1.10 ±0.01	1.15 ±0.00	1.10 ±0.01	1.10 ±0.02
Angle of repose (°)	23.3°	24.1°	26.3°	29.7°	26.4°	25.9°	29.9°	28.4°	27.8°

SB = *Solanum betaceum cav*, PVP = Polyvinylpyrrolidone

Evaluation of tablets using isolated mucilage as binding agents:

The different batches of tablets were prepared using isolated mucilage as binding agent at three different percentages. For comparison, starch and PVP were used as binding agents. The prepared tablets were evaluated and the results of their weight variation, hardness, thickness, diameter, friability, disintegration time and assay were presented in table 13. All the batches of tablets exhibited a good uniformity in content. The hardness of the tablets increased with increase in percentage of binding agent. The tablets prepared with 8% of mucilage showed more hardness when compared to tablets prepared using 4% and 6%. The friability values were decreased with increase in binder concentration. The overall friability values were within that specified limits. The disintegration time of tablets were found to be increased with increase in binder concentration (4% to 8%). This behavior can be attributed to the swelling properties of the mucilage. But the overall disintegration time values were within IP limits.

Table: 13 Evaluation of tablets using different binding agents:

Binders →	**SB**			**STARCH**			**PVP**		
Formulations code → / **Parameters ↓**	**F1 (4%)**	**F2 (6%)**	**F3 (8%)**	**F4 (4%)**	**F5 (6%)**	**F6 (8%)**	**F7 (4%)**	**F8 (6%)**	**F9 (8%)**
Weight variation (mg)	400.1	400.0	401.4	400.0	401.1	400.2	401.0	401.2	400.1
Hardness (kg/cm^2)	4.5	5.5	6.5	4.0	4.5	5.0	4.5	5.0	6.5
Thickness (mm)	4.8	4.8	5.0	4.8	5.0	4.8	4.9	5.0	4.8
Diameter (mm)	10.14	10.14	10.12	10.14	10.12	10.14	10.14	10.14	10.14
Friability (% w/w)	0.3	0.6	0.4	0.3	0.7	0.4	0.7	0.5	0.5
Disintegration time	9min 5sec	17min 8sec	23min /28sec	1min/ 48sec	3min/ 52sec	5min/ 22sec	1min/ 54sec	5min/ 49sec	13min/ 36sec
Assay (%)	99.7	99.6	98.9	100.1	98.8	99.8	98.7	100.2	99.9

***In vitro* dissolution studies of tablets using isolated mucilage as binding agent:**

In vitro dissolution profile of tablets was shown in figure 15 and 16, tables 14 and 15. This study showed that the drug release from the tablets prepared using the mucilage with 4% and 6% concentrations were found to be more than 80% and 90% was found to be less than 80% in 30 minutes. The drug release was found to be increased with decrease in the concentration of mucilage.

From the graph, the drug release of F1 and F2 batches showed a sharp increase, whereas F3 showed less drug release compared to other standard batches. The friability and disintegration time of all the formulations were found to be within IP limits. The drug release of F1& F2 formulations were within IP standard but not F3 formulation.

Table: 14 Standard graph of paracetamol drug

Concentration (µg/ml)	Absorbance (UV)
0	0
2	0.096
4	0.206
6	0.305
8	0.410
10	0.513
12	0.618

Figure: 15 Standard graph of paracetamol drug

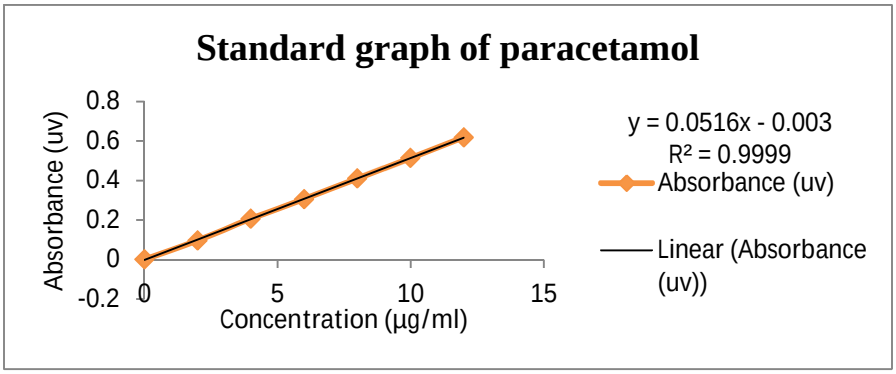
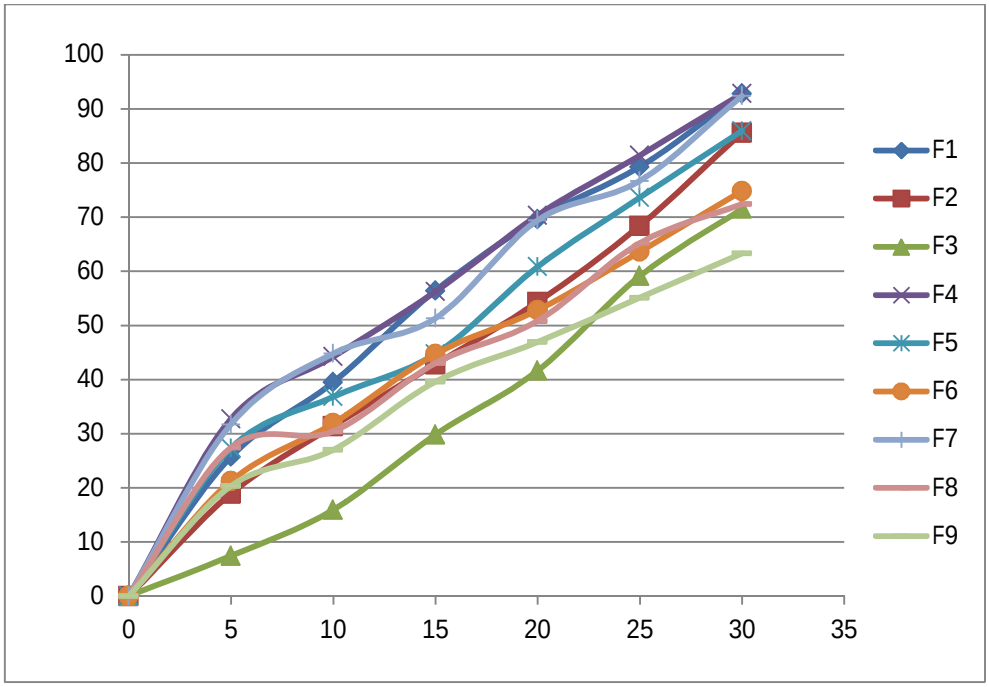


Table: 15 *In vitro* drug release of tablets using isolated mucilage and standard binders:

Binders →	**SB**			**STARCH**			**PVP**		
Formulations code → / **Dissolution time (mins)** ↓	**F1 (4%)**	**F2 (6%)**	**F3 (8%)**	**F4 (4%)**	**F5 (6%)**	**F6 (8%)**	**F7 (4%)**	**F8 (6%)**	**F9 (8%)**
5	25.7	18.9	7.4	32.7	27.3	21.2	31.7	27.4	20.3
10	39.5	31.4	15.9	44.2	36.8	31.9	44.8	30.4	27.0
15	56.4	42.8	29.8	56.2	44.7	44.7	51.3	43.0	39.6
20	69.6	54.3	41.6	70.3	60.8	52.8	69.4	50.8	46.9
25	79.3	68.4	59.1	81.4	73.6	63.6	76.7	65.2	55.1
30	92.8	85.6	71.5	92.8	85.9	74.8	92.4	72.4	63.3

Figure: 16 Comparative dissolution profiles for formulation (F1 to F9)

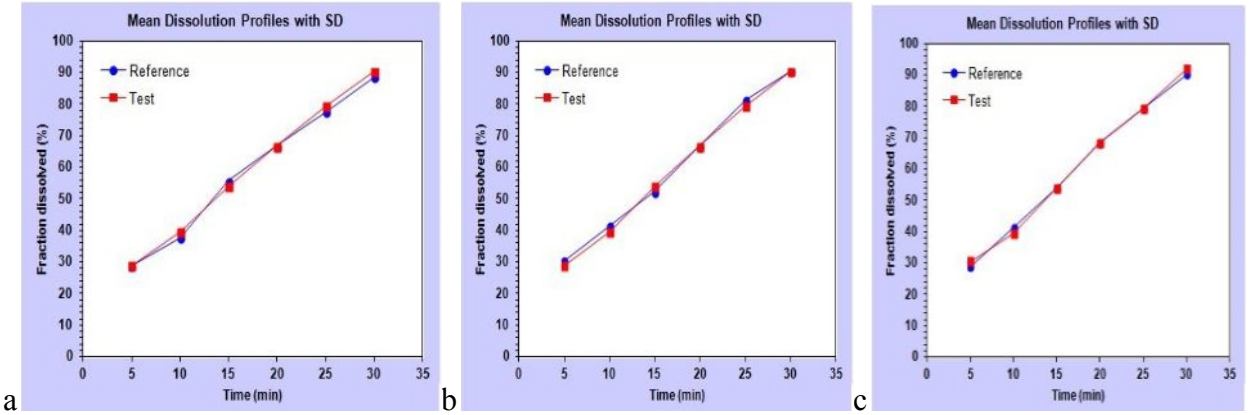


Statistical factors:

Table: 17 Statistical factors

Difference factor (f1)	2.00	1.49	1.99	1.94	1.03	0.99
Similarity factor (f2)	87.71	89.75	87.51	87.51	92.04	92.04
Rescigno index (ξ)	0.0099	0.0070	0.0114	0.0098	0.0059	0.0057

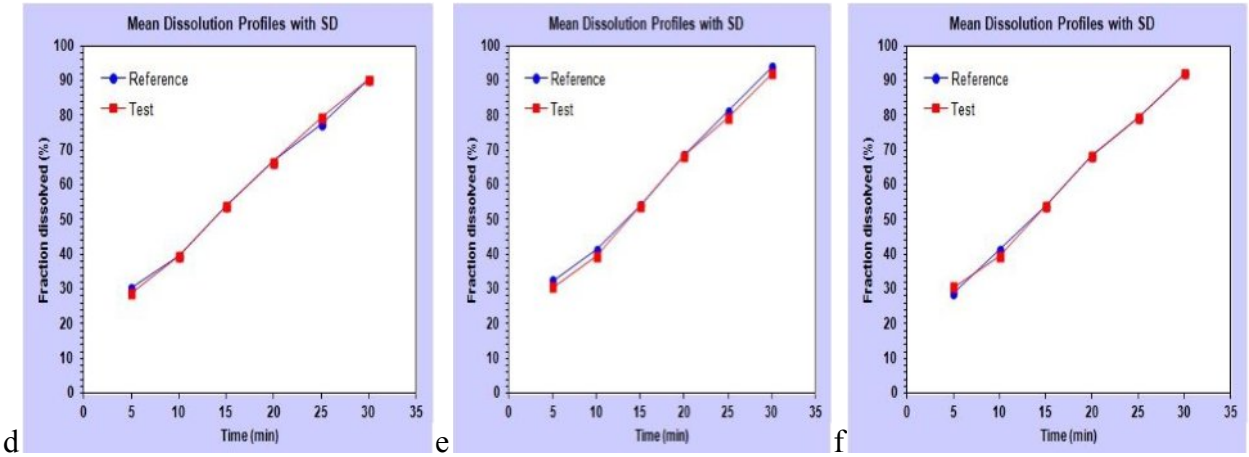
Figure:17 Difference factor of SB compared with STARCH



a b c

F1 Vs F4 **F2 Vs F5** **F3 Vs F6**

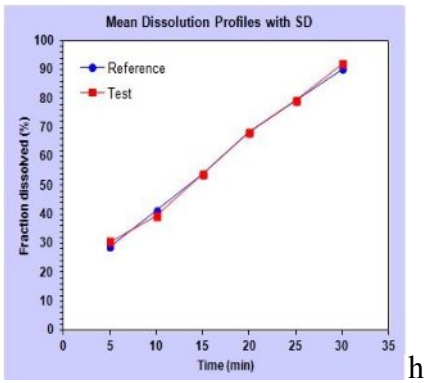
Figure: 18. Difference factor of SB compared with PVP

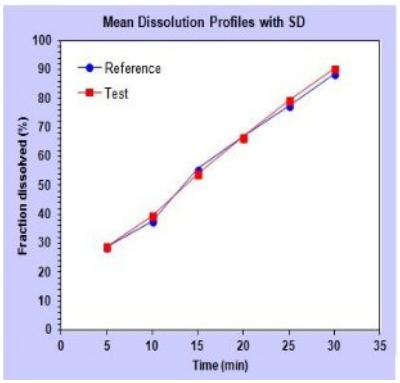


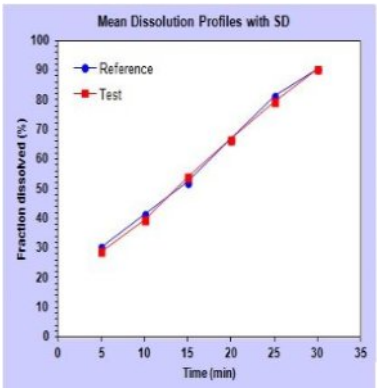
d e f

F1 Vs F7 **F2 Vs F8** **F3 Vs F9**

Figure: 19.Similarity factor of SB compared with STARCH

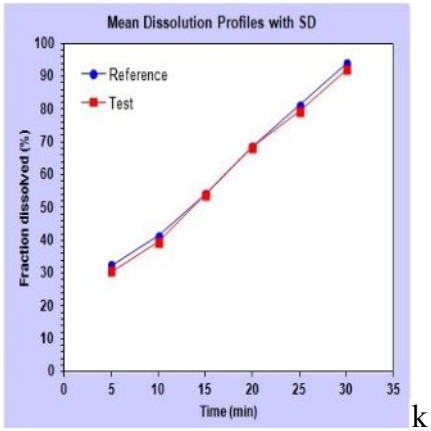
g 

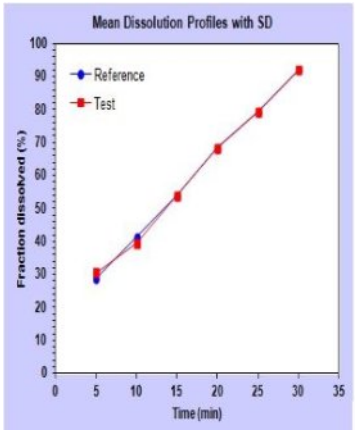
h 

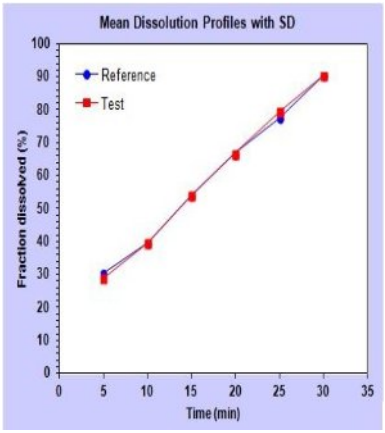
i 

F1 Vs F4 **F2 Vs F5** **F3 Vs F6**

Figure: 20. Similarity factor of SB compared with PVP

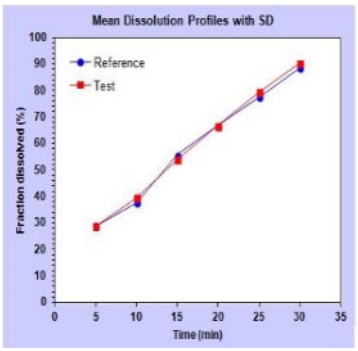
j 

k 

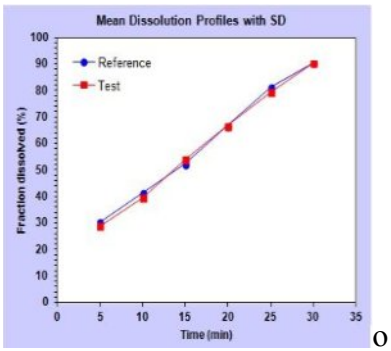
l 

F1 Vs F7 **F2 Vs F8** **F3 Vs F9**

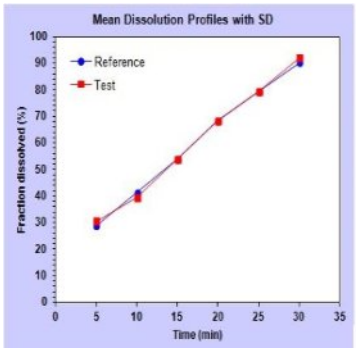
Figure: 21. Rescigno index of SB compared with STARCH

m 

F1 Vs F4

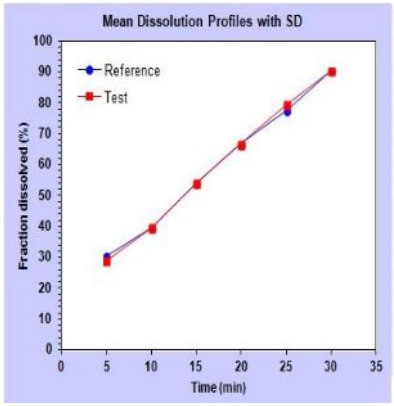
n 

F2 Vs F5

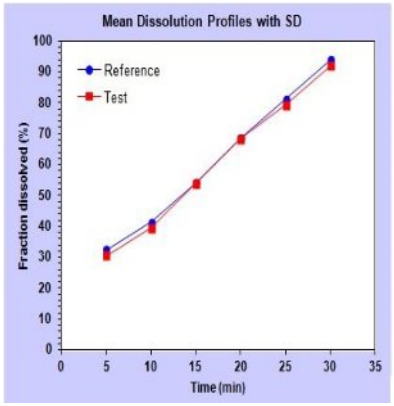
o 

F3 Vs F6

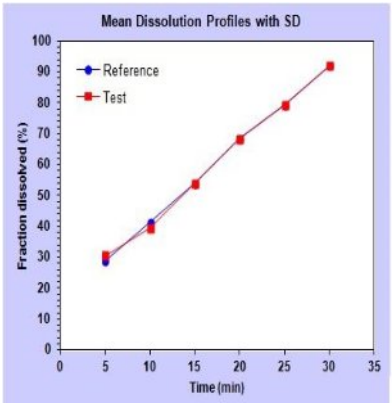
Figure: 22. Rescigno index of SB compared with PVP

p 

F1 Vs F7

q 

F2 Vs F8

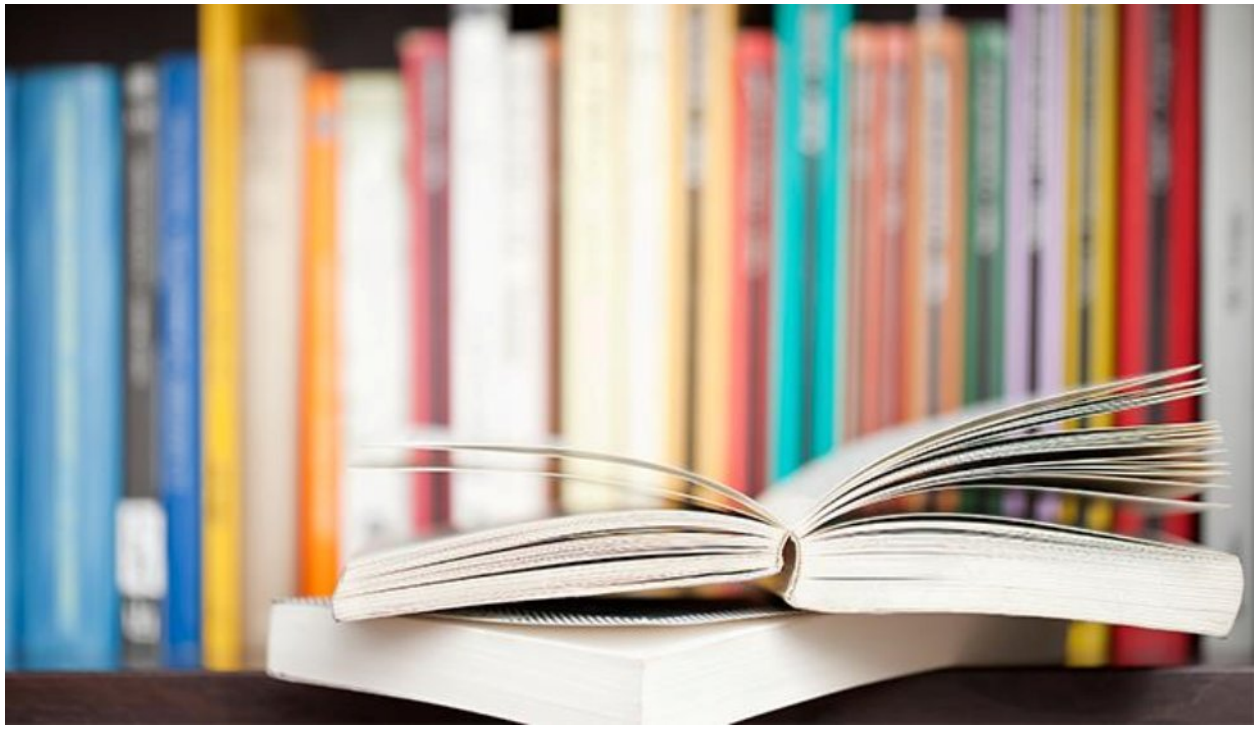
r 

F3 Vs F9

CONCLUSION

CONCLUSION

The market for drug delivery system has come a long way and will continue to grow at an impressive rate. Today's drug delivery technologies enable the incorporation of drug molecules into a new delivery system thus providing numerous therapeutic and commercial advantages. Natural materials readily available, cost effective, eco-friendly, biodegradable and biocompatible due to their natural origin can be extensively used in the field of drug delivery. In recent year, the interest is growing to develop multiparticulate drug delivery system with the use of natural polymer thereby increasing the therapeutic value as well as reducing toxicity. On the basis of this dissertation work , polysaccharide isolated from fruit of *Solanum betaceum cav* shows excellent binding property with no interaction in it comparision with existing polymers. In future the polymer characteristics can be studied for sustain release property and it may be used as a novel polymer in drug delivery system..



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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
भारतीय वनस्पति सर्वेक्षण
BOTANICAL SURVEY OF INDIA
दक्षिणी क्षेत्रीय केन्द्र / Southern Regional Centre
टी.एन.ए.यू कैम्पस / T.N.A.U. Campus
लाउली रोड / Lawley Road
कोयंबत्तूर/ Coimbatore - 641 003
टेलीफोन / Phone: 0422-2432788, 2432123, 2432487
टेलीफक्स/ Telefax: 0422- 2432835
ई-मैल /E-mail id: sc@bsi.gov.in
bsisc@rediffmail.com

सं. भा.व.स./द.क्षे.के./No. BSI/SRC/5/23/2016/Tech. /1449 दिनांक/Date: 26th September 2016

सेवा में / To

Mr. Prasanth R.K.
Final Year M. Pharm.
Department of Pharmaceutics
Karpagam College of Pharmacy
Othakkalmandapam
Coimbatore – 641 032

महोदय/Sir,

The plant specimen brought by you for identification is identified as *Solanum betaceum* Cav. - SOLANACEAE. The identified specimen is returned herewith for preservation in their college/ Department/ Institution Herbarium.

धन्यवाद/Thanking you,

भवदीय/Yours faithfully,

GVSMurthy 26/9/16

(डॉ. जी.वी.एस. मूर्ति /Dr. G.V.S. Murthy)
वैज्ञानिक 'जी' एवं कार्यालय अध्यक्ष /
Scientist 'G' & Head of Office

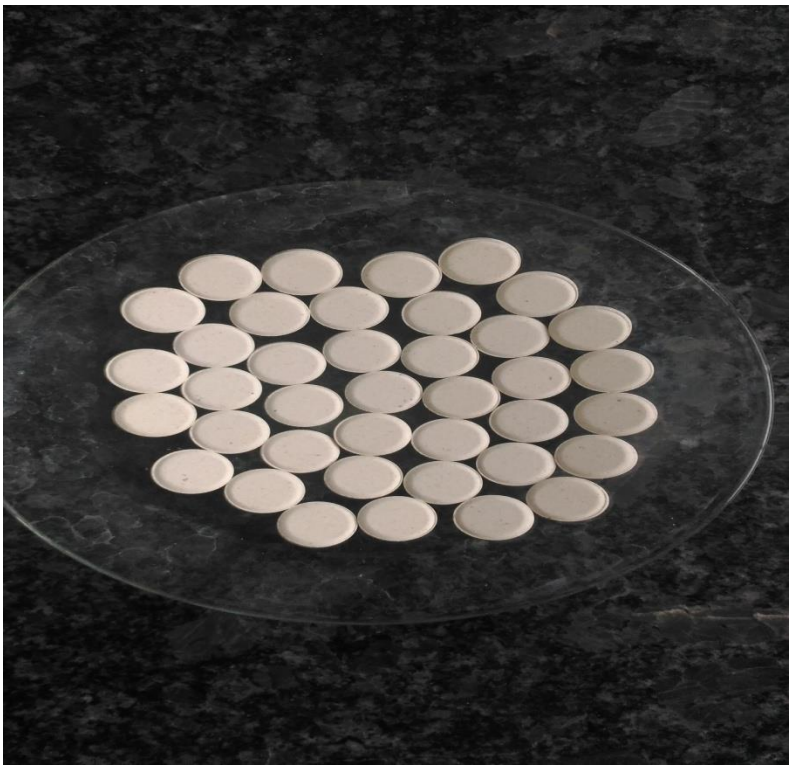
वैज्ञानिक 'जी' एवंकार्यालयअध्यक्ष
SCIENTIST 'G' & Head of Office
भारतीय वनस्पति सर्वेक्षण
Botanical Survey of India
दक्षिणी क्षेत्रीय केन्द्र
Southern Regional Centre
कोयम्बत्तूर / Coimbatore - 641 003.

APPENDICS

Photographs

***Solanum Betaceum Cav* Fruit**

Isolated Polysaccharide from *Solanum Betaceum Cav* fruit



Formulated tablet by using *Solanum betaceum cav* polysaccharide as binder